DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

NATIONAL MAMMOGRAPHY QUALITY ASSURANCE ADVISORY COMMITTEE

Volume II

8:00 a.m.

Tuesday, November 3, 1998

Gaithersburg Hilton
620 Perry Parkway
Gaithersburg, Maryland 20877

MILLER REPORTING COMPANY, INC.
507 C Street, N.E.
Washington, D.C. 20002
(202) 546-6666

P A R T I C I P A N T S

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P R O C E E D I N G S

Introductory Remarks

DR. MONSEES: Good morning. This is the second day of the National Mammography Quality Assurance Advisory Committee. On the agenda today, we will begin with an update on MQSA reauthorization, hear an update on states as certifiers, and an update on the voluntary stereo accreditation program. Then we're going to continue discussing the agenda items from yesterday. So we will begin.

Dr. Finder has to read something here for a minute?

DR. FINDER: I'm going to read the conflict-of-interest statement again, the same one that was read yesterday.

The following announcement addresses conflict-of-interest issues associated with this meeting and is made part of the record to preclude even the appearance of any impropriety. To determine if any conflict exists, the agency reviewed the submitted agenda and all financial interests reported by the committee participants. Conflict-of-interest statutes prohibit special government employees from participating in matters that could affect their or their employer's financial interest.

However, the agency has determined that

participation of certain members and consultants, the need for whose services outweighs the potential conflict of interest involved, is in the best interest of the government. Full waivers are in effect for 13 out of 15 participants because of their financial involvement with facilities that will be subject to FDA's regulations on mammography quality standards with accrediting, certifying, or inspecting bodies, with manufacturers of mammography equipment, or with their professional affiliations since these organizations could be affected by the committee's deliberations. The participants include Dr. Barbara Monsees, Dr. Laura Moore-Farrell, Ms. Patricia Hawkins, Dr. Ellen Mendelson, Mr. Michael Mobley, Mr. Robert Pizzutiello, Dr. Edward Sickles, Ms. Patricia Wilson, Ms. Kendra McCarthy, Dr. Candace Dolat(ph), Dr. Robert Nishikawa, Mr. Roland Fletcher, and Dr. David Winchester. Copies of these waivers may be obtained from the agency's Freedom of Information Office, Room 12A-15 of the Parklawn Building.

We would like to note for the record that if any discussion of states as certifying bodies was to take place in any meetings of the committee, there would be a general discussion only. No vote would be taken and no consensus sought. In the interest of getting as many viewpoints as possible, all SGEs, including state employees, would be allowed to participate in the general discussion so that all

viewpoints could be heard.

Also, several of our members and consultants reported that they receive compensation for lectures they have given or will give on mammography-related topics. However, they have affirmed that these lectures were offered because of their expertise on the subject matter, not because of their membership on the committee.

In the event that the discussions involve any other matters not already on the agenda in which an FDA participant has a financial interest, the participant should excuse him- or herself from such involvement, and the exclusion will be noted for the record.

With respect to all other participants, we ask in the interest of fairness that all persons making statements or presentations disclose any current or previous financial involvement with accreditation bodies, states doing mammography inspections under contract to FDA, certifying bodies, mobile units, breast implant imaging, consumer complaints, and mammography equipment.

DR. MONSEES: Thank you.

Our first speaker this morning is John McCrohan, who will speak about MQSA reauthorization and give us an update.

MQSA Reauthorization - Update

MR. McCROHAN: Good morning. I wanted to say a

few words this morning about the reauthorization of MQSA, and before I go into some of the specifics, I want to mention a few things about the process of reauthorization which I found illuminating.

About a year or a little longer ago, MQSA reauthorization first came to the fore. As you may recall, the original statute which was passed in '92 authorized appropriations for MQSA purposes through fiscal year 1997. And towards the end of 1997 calendar year, in October of 1997, the Senate acted on reauthorization. This was halfway through that particular Congress, which is just now coming to a close, and they passed a reauthorization bill in the Senate which had relatively few changes, and those were minor and technical changes to the original statute.

The House, on the other hand, had not acted by that time and, in fact, really began its activity in the spring of this year. They had hearings last summer. This was before the Subcommittee on Health and Environment of the House Commerce Committee, and these hearings took place, as I said, in the summer, and there were subsequent discussions at the Commerce Committee level. There was a vote at the committee level, and then ultimately there was a vote in the House as a whole. And the House passed this House-based version of the MQSA Reauthorization Act almost unanimously. There was one dissenting vote.

However, this left us in the situation where we had different bills passed by the different Houses of Congress, and that situation needed to be reconciled. This happened in the waning moments of this Congress as we were approaching and passing the 1st of October and as Congress was interested in getting out of town to campaign for the election, which is today.

As it happens, the Senate decided to take an expeditious approach and passed the most recently passed House version of the bill by unanimous consent, and so then all of the parts of Congress had agreed on the same language, and that bill then went to the President for signature and was, indeed, signed a few weeks later, and that only some few weeks ago.

So we now have MQSA reauthorized, and I think aside from learning a bit of civics that I somehow must have missed in high school and college during this process--and it's frankly more complicated than I appreciated--I think the most interesting aspect was the unanimity of support of all of the parties who testified before the House Commerce Committee's subcommittee, which is where the hearings were held, their support in terms of MQSA and its basic approach and their praise for what the agency and the states and the facilities and the committee and so forth have done up to this point with respect to MQSA.

There were people testifying both from FDA and from the General Accounting Office, but also from several consumer-related organizations as well as the American Cancer Society, the American College of Radiology, and so on. There was quite unanimous support for the reauthorization bill as a whole.

There was some debate, if you will, over some difference of opinion on some of the specific points that were in the proposed legislation on the House side, and, indeed, there was some debate amongst the members of the House Commerce Committee about certain of the provisions, and we can touch on that in a moment. But I did want to mention what had happened and also mention in particular the very broad support that the program has from the Members of Congress generally and from the people who testified at the committee hearings.

[Slide.]

You have been given a copy of a document which I guess would be fair to call MQSA as amended. The MQSRA, the Mammography Quality Standards Reauthorization Act of 1998, in fact, consists of a set of amendments to the original statute, and what we have done is to take those amendments and to fold them into the original statute, the MQSA of '92, so that you have what is, in effect, an amended version of that original act.

In due course, and I'm sure with all deliberate speed, we will get an official version of that from Congress, but that has not yet been forthcoming, so I apologize in advance if there's any confusion attendant to the way we undertook to put the two documents together. But I think what you have essentially is the Mammography Quality Standards Act, that is, as it now exists, and that includes all of those amendments.

The act was in effect or has been in effect since it was signed by the President. One of the things that I'll get to in a moment is a situation in which even though the statute doesn't contain any language indicating when a particular aspect of the act will be effective, the House, in putting forward the bill, also put forward what's called the House report or bill report, and this is fairly typical. And you can't have reports on both sides, as was the case with the original MQSA. But in this case, we have a bill report from the House which indicates the sense of the Congress in terms of what they meant by some of the things that they said in MQSRA, and this is particularly significant with respect to one provision that I'll get to in a moment.

But I just wanted this morning to talk about some of the more significant aspects of the reauthorization legislation, certainly not talk about all of the details.

As you can see on this slide, there were a number of technical corrections and minor amendments that certainly may have some effect on the clarity of the act and so forth on some minor points. But I just wanted to go through four or five things this morning that seemed particularly significant.

One, which may be of significance mostly to me, is the fact that the reauthorization was through '02. The original authorization was from '92 to '97, a five-year authorization, which is fairly typical, and when the House and the Senate redid the bill, they just changed the 1997 to 2002, an additional five years. On the other hand, of course, we had already lost a year, if you will, in between '97 and '98, so we really are facing reauthorization again in four years, and so I would expect that we will have not this coming Congress that will be coming in momentarily, but the Congress after that, two years down the road, will be asked to deal with the reauthorization of MQSA again. And that will take place towards the end of that Congress, as it did this time.

The second point that I wanted to mention was there was a significant change in the section with respect to accreditation standards, and that was to insert into the act a new term of art and a new personnel category, if you will. And this is a group called reviewing physicians.

These are individuals who are employed by accrediting bodies to do the clinical image review that's part of the accreditation process, as you know. And the new definition says in part that these reviewing physicians will be physicians as prescribed by the Secretary in the existing part of the statute who meet such additional requirements as may be established by an accrediting body and approved by the Secretary.

As you read that, you'll see that there's a little bit more detail there, but basically we're talking about the fact that now under the reauthorized MQSA accreditation bodies can establish additional requirements with respect to their reviewing physicians. They certainly must be interpreting physicians under the act, but they can now impose additional requirements, presuming that those are approved by the Secretary.

In addition, there are some amendments to the statute which clarify some of the responsibilities of facilities under the statute, and in particular with respect to the issue of retaining the mammograms as part of the patient's medical record. There certainly is continuing to be in the statute the language with respect to the length of time that the mammograms must be retained; but in addition to that, there is clarifying language that makes more explicit the fact that these mammograms--or that the

facilities must, upon the request or on behalf of the patient, transfer the mammograms to a medical institution or a physician or to the patient directly.

There had been--I think there was clear basis for interpreting that that was the intent of the original statute, but this clarification certainly makes it much clearer to facilities that they have that responsibility and that the patients have a right to access to their mammograms, and we hope that that's going to certainly ease the difficulties that have been reported by some in terms of having facilities transfer films in a timely fashion and at a reasonable cost.

[Slide.]

Probably the last two items I wanted to mention were the most significant changes in the statute, the first being very significant to facilities and patients, and the second being of most significance to the FDA at the moment. The first item is the direct report to patients, and this was alluded to yesterday. In addition to the requirement that existed in MQSA previously, in addition to the mammography report being provided to any referring physician or to the self-referred patient if in that case there is no physician, the reauthorized MQSA requires that for each patient, be they self-referred or referred, for each patient a summary of the written report, a summary of the

mammography report shall be sent directly to the patients in terms easily understood by the patient.

We got into some discussion of that yesterday on some of the implications of that. But that's certainly a very significant change for facilities as well as for patients. It in my view represents, in effect, an expansion of the practice that the facilities would have had already with respect to how they interrelated with their self-referred patients. But now all patients are going to be getting a copy of this lay summary of the medical report or mammography report directly from the mammography facility as opposed to previously where they would have gotten their information in the large proportion of cases through the agency or the referring physician.

Finally, the MQSRA called for a demonstration program with respect to inspections. The intent of this program is to determine whether or not there is a set of selection criteria that the agency could use to select facilities that might be inspected less often than annually and still provide the same assurance of quality that's provided currently by the mandated annual inspection. The motivation I think for this is the fact that when we first started inspections under MQSA, even in the initial year, we had about 30, 35 percent of facilities with no findings inspections. That's grown now to probably 60, possibly 65

percent of facilities with no findings inspections.

While we might expect reasonably for that number to go down when the final regulations go into place, I think it would be reasonable to suppose on the basis of past experience that we would in the succeeding two years or so get back to about where we are today. And people have raised the not unreasonable question about what value is added by continuing to inspect facilities and continuing to establish on an annual basis that there are no problems. And so that brings up the obvious question of can you re-establish that there are no problems in those facilities on a less-than-annual basis and thereby still provide assurance of quality.

So there was this call in the MQSRA for a demonstration program regarding the frequency of inspection, so the Secretary is due to establish that demonstration program with selected facilities who would be inspected less often than annually, I presume biennially, and then establish whether there are a set of selection criteria that will work.

The statutes says, interestingly enough, that this is not to begin before April 1st of 2001. We had spoken directly with House staff and made the point that the final regulations are going into effect April 28th of '99, that we felt that facilities needed to have about a year to get

comfortable with all of the requirements so everybody could have had an inspection under the final regulations before anything began, then we could use the inspections that would begin in April of 2000, and for that succeeding 12 months as, if you will, a baseline year, and we could, in fact, use performance in that baseline year as one of the possibly several criteria that might be used to select facilities for participation in the demonstration program.

So the first year--and we haven't designed the program yet, so I'm being a little speculative, but presumably the first year in which some facilities in the demonstration project wouldn't have an inspection would be the 12 months beginning April of 2001. The presumption then would be in the following 12-month period everybody would be inspected again, and you'd look at the results and you'd see were the results any different for facilities that were in a certain category, met whatever the selection criteria are that you're considering, who did get an annual inspection every year, were they any different from the facilities who didn't get an annual inspection in one of those years. And if you establish that there wasn't any difference, then presumably you've established that going to a biennial inspection for that group of facilities isn't going to have a cost in terms of reducing your assurance of quality.

We have a lot of work to do, as you might expect,

in terms of designing the demonstration program. We've begun some preliminary internal discussions on those points, and those will be going on for a fair while, I think. And as you might expect, there are a fair number of hurdles to be gotten over in terms of designing a study that will actually answer the question we want to answer. So I don't expect to see anything substantive in terms of a plan for some while, but presumably we'll be back at a future occasion to let you know where we are on that.

That was basically all I wanted to talk about this morning unless you have any questions about the reauthorization act that you'd like to raise.

DR. MONSEES: Thank you for your presentation.

I neglected to point out--and you probably all know, and it's written on the agenda--that Mr. McCrohan is the Director of the Division of Mammography Quality and Radiation Programs. And I'll take questions now pertaining to this, or if you would, any other general questions.

MR. McCROHAN: Sure.

DR. MONSEES: Anybody from the panel who has a question? Yes?

DR. NISHIKAWA: John, in terms of patients getting access to their mammographies, does that imply they have the right to their original mammograms or copies of their mammograms?

MR. McCROHAN: The originals. At least that's the way we're interpreting the language, and I think it's the reasonable interpretation.

DR. MONSEES: Okay. Good question. Any other questions?

[No response.]

DR. MONSEES: Thank you very much.

Okay. We'll move on to an update on states as certifiers by Ruth Fischer, who is the chief of the Mammography Standards Branch.

MS. FISCHER: Good morning. The update that I would like to tell you about today is what is happening with our demonstration project.

[Slide.]

It began in August of this year, and it runs through August of next year.

[Slide.]

And the participating states that were selected for this program were Iowa and Illinois. We've now finished the first quarter of operation, and as you might expect, start-up in something that's brand new is the most difficult time. We're also looking to the demonstration project to bring us answers to problems so that when the regulatory program finally begins, which we anticipate in two years, many of the kinks will be worked out. So I think in that

respect it's good we're having some problems because we're learning from it.

[Slide.]

I'd like to go over the application process that we used. It was in two phases. I believe that I talked to you about these areas the last time I spoke to you and when I did an orientation for new members, and this has not changed. This is the documentation area in the written application process. What I'd like to tell you about in technical staffing and training is that we added a category dealing with information systems personnel. Probably one of the--the most critical operational element that we're looking at is electronic data transmission. So we are requiring that the states do have designated information systems, people on staff to assist with this.

Also included in technical staffing and training are consultants who will deal with mammography practice concerns, and that means clinical issues. So, therefore, the states had to provide us with qualified MQSA physicians and medical physicists that could be used as consultants, and I would say that in both instances, the caliber of those physicians certainly exceeds that of just meeting the MQSA requirements.

[Slide.]

Phase 2 is the actual testing of the information

systems. I think what we learned from this is, according to our computer folks, the transfer of data is relatively simple. However, that's the computer folks talking, and it's, by and large, the program people who are actually doing the transmission. So although we found that the systems worked, the implementation of it became more complicated.

What we would like to do next year when we reopen this again is to actually have instruction and testing with the personnel who are going to actually be using it on a daily basis, and that would be program people.

[Slide.]

We're evaluating the program according to performance-based criteria. Therefore, we're looking for results, outcomes. And the process by which they are achieved is not as important to us as the end result. And we have three categories for evaluating each of the performance indicators that were on the application. We will be doing an evaluation later this month to take a look at what's gone on in the first quarter. It will not be every single item because some of the time frames don't kick in until four months into the program and so forth. But whatever is applicable to date we'll be looking at, and we'll use that to work with the states if there are any categories that are not straight satisfactories.

[Slide.]

This is looking at some of the issues that we will be evaluating, and it is, again, how are they doing on the way to completing facility inspections annually; how are they handling inspections which might have to be deferred for one reason or another, how are they rescheduled; the timely resolution of the findings that the inspection itself is complete and well documented; follow-up inspections are conducted for appropriate reasons; that there's appropriate and prompt enforcement; and that all the issues surrounding inspector quality assurance which we have in place for MQSA, our own MQSA inspectors, are met with the states' inspectors.

[Slide.]

Finally, in certification program areas, we'll be looking to make sure that whatever the accreditation body transmits as the appropriate status of a facility is reflected in the appropriate type of certificate; that the certificates are mailed in a timely manner. We presently use a two-week standard to make sure that from the time that we get data that the certificate is printed and sent out. Often we can do it in less, but that's what we--the parameters that we also gave to the states. We will be looking to see, if anything has been done in the suspension and withdrawal area, that it was done according to

appropriate criteria; that there's prompt investigation and action, and particularly for facilities who may be operating without a certificate. Certainly in this area, the states are very close to the situation and can spot this. And when you were talking about patient notification and that being prompt, I would fully expect from our past experience that those facilities which might be of most problem will be targeted quickly under the states as certifiers program.

Also, we'll be looking to see how inquiries about the program are handled. We have a hot-line right now which we use to field volumes of calls, and we still have a great number of calls that come in directly to the division that we answer. So we'll be looking to see what the parallel system is in the states and that there are appropriate appeals processes.

These last two slides, again, are evaluation criteria that there are definite guidelines to the states for what is timely, what is an appropriate process and so forth.

We anticipate that a notice for the second year of the demonstration program will go out later this month or by mid-December.

DR. MONSEES: Thank you.

Do we have any questions? Yes, Dr. Dempsey?

DR. DEMPSEY: Ruth, at the outset, you mentioned

that you did encounter some problems?

MS. FISCHER: The problems are primarily electronic data transmissions and understanding what we meant by closing out a report. For example, if the ACR transmits us data about the status of a facility and then the states taps in and is able to get that data immediately, when they mail the certificate, at first they didn't understand that they were supposed to send back a date when they also did that. So there was just some confusion about what we wanted feedback on.

DR. DEMPSEY: So the problems were really data transfer problems?

MS. FISCHER: So far.

DR. DEMPSEY: The other thing is you had mentioned in your presentation that process was not as important as the end result. Are there efficiency parameters, nevertheless, that you look at? Because you could get an end result but have it take twice as long.

MS. FISCHER: Well, I think that would be covered under the times in which we asked for resolution of inspection findings, the times in which certificates must go out, the times in which data is uploaded to us.

DR. DEMPSEY: So there are time limits internally.

MS. FISCHER: Yes. And that's one of the ways we can actually do some quantitative evaluation, because we

have these.

Yes, Mike?

MR. MOBLEY: Ruth, you talk about it being performance-based and everything, but then you're--and I'm as guilty as anyone. But you're measuring these kinds of things like time and how fast somebody does something and the quantity or percentage or whatever. One of the things I wondered about here is that in doing this, and particularly allow states to take over a program, there's the potential that there may be some new mechanism developed or a new process developed that enhances a program. And I'm wondering, is there anything in place or has anybody thought about putting in place something that looks at after a period of time, a couple of years or whatever, a state has been running its program, do we see better quality images, lower doses, better delivery of the services?

That's the real performance indicator in my mind. That's the absolute performance indicator, if we have a better product delivered to the consumer as an end result. And I don't see anything here that captures that.

MS. FISCHER: I think that certainly the indicators that we used for this first year were, you know, the best we could generate in the amount of time that we had. Certainly the point of the program is to note keep this cast in stone, but to reflect where we should be going

and what we're learning. And certainly I think that what you brought is very important.

I think the less tangible parts of the program are those things that deal with the resolution of findings, the facilities operating without certificates, what happens when the states need to go to their physician or medical physicist to resolve some clinical issues. And to date, we just don't have any experience in that yet. I would assume that over the course of two years in a demonstration project those issues will come up. So this is just our first-year model.

MR. MOBLEY: Well, I threw out the broad question first. Now I'll target my question.

MS. FISCHER: Don't give me a hard time.

MR. MOBLEY: No, no, not at all.

One of the experiences the states have had in a number of different programs is that when the feds are doing their part, they do their thing as they do it; and then when we attempt to do our part, we're held to a higher standard, sometimes a significantly higher standard.

Is that the case here?

MS. FISCHER: Absolutely not. Let me tell you a little story about that.

We learned from the Nuclear Regulatory Commission that that was precisely what happened with their agreement

state program, and the GAO ripped them to pieces over evaluating themselves one way and evaluating the agreement states another way. First of all, scientifically, you cannot conduct an evaluation that has any validity by comparing apples and oranges.

Interestingly enough, four and a half years ago, when I first came to the government, we saw all these findings, and I was talking about, well, we really need a program where we're evaluating ourselves exactly as we are the states. And someone said to me, well, we don't do that; you haven't been in government long enough.

But with the progressive leadership we presently have, we certainly are going to look at all the characteristics of our own program the same way, and then also by doing that, we can adjust the degrees of what we're looking at. Perhaps time frames might be adjusted, or percentages adjusted, or, you know, so we will be looking at both.

MR. MOBLEY: Thank you.

DR. MONSEES: Yes, Dr. Sickles?

DR. SICKLES: You mentioned this is a two-year demonstration project. In the second year, will you be expanding to have more states, or will you just keep with the two that you now have?

MS. FISCHER: Depending on the performance at the

end of the year of Iowa and Illinois, they can opt to renew. We will also open it to new states. However, I don't have a ny kind of indication as to what the interest or response is to coming in, you know, for the second year.

MS. BROWN-DAVIS: Ruth, in your presentation, you mentioned--or there seemed to be some correlation between the state certification program and patient notification, some correlation in your mind. Is that correct? And so I'm wondering if your expectations are--what are your expectations around patient notification as it relates to the states? And if, in fact, there is that correlation, what--it sounds as if the horse may be--or the cart may be before the horse for some. I'm just not clear on exactly what that relationship is.

MS. FISCHER: Patient notification is probably the most extreme of enforcement actions. I mean, you know, it's something that would not be entered into without the utmost seriousness.

The states are required to be able to have a process to do this should it be necessary, and my point was that the states very much know their good and bad players. And they may be quicker than we are to identify a really problem facility, and if it should bear out, it could be that action might occur sooner rather than later.

MS. BROWN-DAVIS: Well, now, do the states have a

time frame? I mean, as you're certifying, is there a stated time frame for the states to let patients know that there's a problem?

MS. FISCHER: No.

MS. BROWN-DAVIS: Do you know specifically how the language is written? Do you remember?

MS. FISCHER: It's not--this goes back to yesterday's discussion in which what is called for in the regulations, in the final regulations, is that this mechanism is in place, but just as yesterday's discussion didn't resolve anything about the time in which it occurs, neither does this.

MS. BROWN-DAVIS: Thank you.

DR. MONSEES: Any other questions?

[No response.]

DR. MONSEES: Thank you very much.

MS. FISCHER: Thank you.

Voluntary Stereotactic Accreditation Programs - Update

DR. MONSEES: We'll move on. The next topic is voluntary stereotactic accreditation programs. The update will be given by Pamela Wilcox-Buchalla, Senior Director of Accreditation Programs, American College of Radiology.

Do we have a representative from the American College of Surgeons?

MS. WILCOX-BUCHALLA: Apparently not. I had

understood that Dr. Winchester was going to be here to speak to their issues, but he's not here.

DR. MONSEES: Okay. Why don't you proceed?

DR. FINDER: I was under a different impression, that you two had worked it out that you were going to present both sides.

MS. WILCOX-BUCHALLA: Well, I can do that. I have the information, but I was not aware that he was not going to be here. I had hoped he was going to have some more current information, something new that I don't have, and I'll tell you about that. They are working on a survey, and I had understood he was going to have some preliminary results from their survey when he was here.

I was interested to see that Dr. Finder gave me half an hour on the agenda for what he told me was going to be a five-minute update. So I'm prepared to be somewhere in between 5 and 30 minutes.

[Laughter.]

DR. FINDER: We wanted to give you flexibility.

MS. WILCOX-BUCHALLA: I love it. You know, the FDA is really good at that. Isn't that what the "f" stands for?

I'll start talking about the ACR program and where we are today. Interestingly enough, the universe being much smaller, meaning that we have about 2,500 to 3,000 units

across the country, percentage-wise we're probably at about the same place with stereo that we were with mammography this far into the program, being a year and a half. That's the good news. The bad news is that if we only have 13 months to get the rest of the facilities in the program, it's going to be very difficult.

At this point we have 385 facilities with 390 units that have applied for accreditation, so that's about 13 percent of the universe. Total facilities accredited is 289. The initial deficiency rate is slightly higher than what we saw in mammography when it first began in '87, initial deficiencies of about 42 percent. So for those of you who may be confused about terminology, when we say initial deficiency, that's when a facility applies, may have problems with either clinical images, phantom dose, et cetera, and then they still have an opportunity to correct problems, reapply, and if they don't pass on that second attempt, that's when we consider it a failure. And in mammography, under the law, when they fail they have to cease operating. Obviously, under the voluntary program, that's not true. But we're still requiring the same kinds of action, detailed corrective action and resubmission.

The repeat, for those that have had a deficiency initially and then reapply after corrective action, we're seeing a deficiency rate of about 17 percent or a failure

rate of 17 percent, which is, again, very comparable to what we've seen in mammography all along.

I think one of the issues that will be very helpful is we are developing and completing a quality control manual for stereotactic that should be out by the end of the year, and that will look at issues related to routine QC, phantom imaging, and dose.

Again, another interesting parallel to mammography is that we are seeing dose failures of about 10 percent, which is about what we saw with mammo in '87. And I think that goes back to facilities not doing routine QC, learning the process, looking at the issues, and getting more involved with their physicists.

Now, why is there not a higher level of participation? I think that some of the things that pushed the mammography accreditation program along included increased emphasis on screening for all women by the Cancer Society, and, of course, this doesn't have a parallel process. So we're not getting that community interest, the media push, the Cancer Society push that would help us get facilities into process.

We have included information on our Web page. The ACR and the American Cancer Society have included articles in both of our bulletins multiple times about what the process is, what the criteria are for physicians, and that

if facilities don't participate, it will become mandatory and regulated in 2000. That really hasn't been very successful in pushing, so I think we need to look at some other ways to get people aware of what's going on and get up the level of participation.

One of the other big motivators we had with mammo was the State of Michigan, which had a very big Cancer Society screening program in '88 and then passed legislation in '89 that required facilities. As that went along, again, media interest really generated facilities' participating in the accreditation program.

One of the other things I have not heard much of is facilities marketing themselves as accredited, and, of course, that's always been--that pocket is where people really get interested in participating in some of these programs. If their competitors are accredited and women know to go there, then that's what happens. So we're not seeing that particular issue either. We need to look at other avenues. We need the support of the FDA in getting facilities participating in these programs.

I'm not sure, when FDA staffers go out and do presentations, how much this is discussed. If there's anything we can do to help with that, we'd be glad to do that.

Finally, the status of the ACR and the American

College of Surgeons agreement. As I told you last time, the agreement has been signed off on. We also now have a contract with the College of Surgeons to provide services for accreditation. The way the process will work, I just met with College of Surgeons staff a couple of weeks ago to finalize the logistics, and what will happen is that facilities will apply directly to the College of Surgeons; they will review the credentials for the physicians. If they meet the criteria as outlined in our agreement, then they will forward the application to the ACR, at which point we'll send them testing materials. We will look at the credentials for technologists and physicists, their QC program, and evaluate the clinical and phantom images and provide the dosimeters.

So only the physician qualifications piece will actually be directly done by the College of Surgeons. Accreditation will be awarded by the College of Surgeons. It is not a joint program. They are independent programs, and that's what our leadership agreed to.

The College of Surgeons also sent out a survey approximately two weeks ago to all of their fellows asking who's doing stereotactic biopsy, how many units they have, how many physicians are doing it. And the initial reaction to that survey is to be generating more interest. Staff tells me that they've had a number of phone calls from

people who are interested in applying as a result of the survey.

The piece that I thought Dr. Winchester was going to have was whether there were some preliminary results from the survey about how many surgeons are actually doing this. And it may be that it's just a little too early to have those results. But that's going to be an important piece both for your work in determining whether we're meeting the requirements to have a significant percentage apply, and also for us to be able to plan our workload in terms of being able to do timely review.

We have completed revisions to documents so that the Cancer--I keep saying Cancer Society. I apologize. ACS is ACS. We tried to get them to call themselves ACOS, but they didn't like it. So the College of Surgeons will be mailing applications out to facilities sometime this month, and we expect to actually be receiving applications back by the first of the year, and we should be able to move ahead rapidly in 1999. Hopefully I'll have more information, or Dr. Winchester will, when you all meet in the spring.

Are there questions that I can answer?

DR. SICKLES: Two questions. First, if I heard you correctly, the survey that the College of Surgeons is doing was sent to follows? That's not members, that's fellows.

MS. WILCOX-BUCHALLA: Correct.

DR. SICKLES: So it's a subset of what's actually going on.

MS. WILCOX-BUCHALLA: Right. They are also going to send a slightly modified survey to those facilities that are accredited under the College of Surgeons Cancer Commission. So that may give us another piece.

Interestingly enough, at this point the College of Surgeons is saying they will only process applications from people who are fellows of the College of Surgeons. And if someone wants to apply and is not a fellow, they'll be encouraged to become a fellow. If they choose not to, they still have the option to come back to the ACR, and, in fact, we do have--just last week, we accredited the first surgical site under the ACR program, Dr. Phillip Israel's facility, and he is also a liaison to the ACR Stereotactic Committee.

DR. SICKLES: Are you aware of the percentage of College of Surgeons members who are fellows?

MS. WILCOX-BUCHALLA: It's very high. No, I couldn't tell you exactly what it is, but it's very high.

DR. SICKLES: Okay. It's not like the ACR where a much smaller percentage are fellows.

MS. WILCOX-BUCHALLA: Right. I don't really have a handle on what the difference is between a basic member and a fellow, but I have a sense that it doesn't require the

same level of experience and application process that the ACR's fellowship requires.

DR. SICKLES: Okay. I had one other question. What, if any, developments are there to report in negotiations that you and the College of Surgeons might have with third-party payers to tie reimbursement to certification?

MS. WILCOX-BUCHALLA: As of this point, we have not made any initiatives with any third-party payers about stereotactic. I think one of the issues was to resolve and move ahead with the College of Surgeons first. We already have some relationships for some of our other programs, and I think it should be a fairly easy tie-in. And we should move ahead with that. That would certainly be a good way to get people to participate, wouldn't it?

DR. MONSEES: Does the American Cancer Society maintain an 800 number database for consumers for this, just like they did for the voluntary accreditation program when it first began? People could call a number and get the name of a facility that was accredited under the voluntary program. Can they do that for this?

MS. WILCOX-BUCHALLA: Yes, they can. We provide a list of those sites that are accredited by ACR, and we will provide this same list for the College of Surgeons facilities.

I have a sense that women are not as aware because it's at a point, from a personal perspective, that I think when a woman is being told that she needs a biopsy, she's not--she's going to go wherever her physician tells her to go, and she is less likely to be more assertive about these issues. And, again, that's a public education issue that we probably should find some ways to work with the Cancer Society on.

DR. MONSEES: I have one follow-up question, and I will entertain questions, of course, from the panel. Maybe we'll fill your time slot.

Are most stereo units, do you think, in places that have mammo units? So, in other words, would it help to have the inspectors from the FDA, when they go out and do their annual inspections, comment on the fact that there's an accreditation program and that if participation isn't doesn't done on a voluntary basis it will become mandated? Are most of them housed in centers where there are mammo units?

MS. WILCOX-BUCHALLA: I certainly think for those that are done by radiologists that's true. I had understood that FDA was going to look at whether they could encourage inspectors to do that, and I have heard anecdotally that some inspectors mention it, particularly--well, Arkansas requires stereotactic accreditation and Massachusetts will

as well. But I have heard some anecdotal reports.

We did send applications to all mammography facilities when the program began about a year and a half ago. That may not be true at all for surgeons, and that's one of the pieces of information they're trying to get through the survey. I think it's unlikely that most surgical facilities have a mammography unit. I think that would be unique.

MS. BROWN-DAVIS: Can you expand a bit on how you see the FDA assisting in getting people to participate more in a voluntary accreditation?

MS. WILCOX-BUCHALLA: A couple of ways that they might do that is, one, a bigger emphasis or an emphasis on it in the Website, an article in Mammo Matters, and encouraging or actually perhaps even giving some kind of a news sheet or PR piece that the inspectors could use when they go into a site to make facilities aware. I think there are probably some pretty straightforward things that can be done, but if they're not done soon, the chances of being successful--

MS. BROWN-DAVIS: Has this been discussed prior to--

MS. WILCOX-BUCHALLA: I believe that we talked about that the last time, too.

MS. BROWN-DAVIS: Okay.

DR. MONSEES: Would it be possible to publish participation figures when we get the survey information, not wait until the next meeting but get the update from the American College of Surgeons and put that into the article so that people are aware of how far behind the voluntary accreditation program is?

MS. WILCOX-BUCHALLA: Sure.

DR. MONSEES: And understand how compelling the reason might be to get as far forward as possible. I'd love to see that.

DR. DEMPSEY: Pam, on the dosimetry failures, the percentage again was?

MS. WILCOX-BUCHALLA: Ten percent of the failures included dose failures.

DR. DEMPSEY: Dose failures. Were they digital machines or analogs?

MS. WILCOX-BUCHALLA: Mostly digitals.

DR. DEMPSEY: The second question is to Dr. Finder. Given the fact that there is now a signed agreement between the ACR and the ACS and an initiative is, if you will, off the ground, has the FDA stated any specific target goals in terms of dates or percentage participation that they will require before looking at mandatory regulation?

DR. FINDER: As you might remember from the last meeting that we tried to get some dates and numbers set

down, there was no consensus as to the exact number or date. Now, we are trying to encourage in as many ways as possible and are looking for all different ways to encourage participation in this program. Again, we feel that at this point, the voluntary program is still the way to go as long as we can get enough participation rather than promulgate regulations.

However, we are prepared to go down that pathway if necessary. I think some of the suggestions that have been brought up were brought up last time, too, and some of them have been tried and have not been as successful as one would like. But that doesn't mean that they still won't succeed given enough time.

I think it requires that the underlying basis be established. ACR and ACS have finally got their program set, and I think that we'll see more participation as time goes on. But the FDA is committed to this process. In fact, at RSNA we plan to make a presentation--well, part of our presentation is about this or will be about this to encourage facilities to do this.

DR. MONSEES: How about also having the manufacturers perhaps send out and encourage participation in the voluntary accreditation program? Is there any precedent for that, do you know?

MS. WILCOX-BUCHALLA: I'm not aware of any

precedent. You know, perhaps if the request or the emphasis came from NMQAAC from FDA, that might be helpful.

DR. PIZZUTIELLO: My experience is with facilities, and what facilities get the most uptight about is inspections. It brings back, I think, memories of high school and college final exams for most people, and everybody likes to avoid those. They get nervous about it. And I think it would be very effective if the inspectors were able to say to facilities: I know how much you love me coming and interrupting your day and taking your time to do this; if you have a stereotactic unit and the numbers don't come up to where we need them to be, then you can probably expect to see me twice as often, and I'm sure you'll really relish that; if you don't want to see me that often, then I encourage you to get the message here.

The other thing that occurred to me was you drive along the streets of many little small towns, and they'll have United Way Giving Fund or something like that, and they have this target of, you know, X hundred thousand dollars they have to raise, and the level goes up like in a thermometer. And that might be something that the FDA could publish, maybe just a little blip in Mammography Matters regularly to remind people that we have a long way to go and that we have a target of whatever the time is, 2000, and I think those two methods would help.

DR. MONSEES: Did you want to make a comment first before the next question?

MS. WILCOX-BUCHALLA: Well, one other avenue that might be successful in getting some attention might be the Society of Breast Imaging, and they have done, I think, at least one short article, but perhaps some of the panel members are active in SBI and could work on that issue.

DR. MONSEES: Again, the inspectors and the Society of Breast Imaging and the RSNA are all targeted at radiologists, not really at surgeons.

MS. WILCOX-BUCHALLA: Right.

DR. MONSEES: We need to hear the surgical piece.

Yes?

MR. MOBLEY: Several comments and maybe a question or two. I remember our meeting--I believe it was my first meeting with this group--when we discussed this, and we had, I think, a fairly significant discussion. At least I know I had some very specific concerns about this voluntary effort and not having some rather explicit goals that the voluntary group that were trying to do this could work toward. And as I remember--and I can't tell you what those goals were at the time, but as I remember, I stated some explicit expectations on my part, and I don't think the committee agreed with that necessarily. But I guess that's certainly out there, and I think it should be a driver, as a minimum.

And I will go back and review those and see where we stand at this point in time.

I'm a little concerned--and, Pam you didn't say this; I'm saying this. But I'm a little concerned that we as a committee and that FDA has pushed these entities to develop this voluntary program, and it seems like that we're not doing our part in supporting the effort. And I think that FDA needs to look at what it is that they're doing and pull all of their different entities--I mean, MQSA is just a small part of FDA. There's all kinds of initiatives ongoing within FDA that I think could be brought to bear to deal with this issue and make it a broader issue with the public and with the various physician specialties.

Now to the questions. You mentioned that the College of Surgeons was going to award the accreditation for--and I may not be using the right term there, but the accreditation for their personnel, but that you are doing, the ACR is doing the evaluation of the facilities, the operation, et cetera.

In your agreement with them, is there some methodology or requirement that says that you have to issue the approval for the facility before they can issue the accreditation for that facility?

MS. WILCOX-BUCHALLA: It's actually very much a subcontract, Mike, and what will happen is, if based on

documents submitted to them the physician meets the criteria in our joint agreement, then we do the rest of the process. And although we will actually do the evaluation and issue the report, the report will come from the American College of Surgeons. It will have American College of Surgeons' names and logos on it, but it's actually our evaluation. And then we'll provide back to the College of Surgeons those results, copies of actual individual reports as well as aggregate data on the success or deficiency rates for their sites.

So it's exactly the same as our process, but it's like we do for California. We review their clinical images, but the accreditation comes from California. We're reviewing everything in stereo except physician credentials for the College of Surgeons, but the accreditation is from the College of Surgeons.

Does that make sense?

MR. MOBLEY: Yes, that makes sense. But I'm going to bore in here because I--I mean, I believe that your process is accepted. You know, you've been through this. It's been accepted by the FDA. I'm just a little concerned that maybe you go through that entire process--and I'm not saying this--I'd certainly welcome a surgeon to jump in here or a representative of the College of Surgeons to jump in here. But I just have to resolve this issue in my mind.

You go through your process, and you find that the facility is deficient. And then the College of Surgeons looks at it through their process, and they say, oh, we got a good physician here, he knows what he's doing, he's a good surgeon, and we're not sure about whether ACR knows what they're doing or not. But just because he failed here and his images aren't adequate, we're going to approve him, anyway.

What precludes that from happening?

MS. WILCOX-BUCHALLA: The way the contract is written, any appeal relative to the portions that we perform--clinical image review, phantom, dose--comes to us. The facility physician can write to the College of Surgeons and request the appeal, but we've been recognized via the contract as the experts in that area. So we will be holding them to the same standards we hold anybody else to.

MR. MOBLEY: All right. So the standard is the same; the appeals process is the same. It just goes through here as an administrative function.

MS. WILCOX-BUCHALLA: Right.

MR. MOBLEY: Okay. Thank you.

MS. WILCOX-BUCHALLA: Both organizations have policies that preclude joint accreditation programs, and so that's why it's really a subcontract basis. But it doesn't change the standards in any way.

MR. MOBLEY: And I don't have a problem with that at all. I just wanted to make sure how it worked, and that sounds fine.

MS. WILCOX-BUCHALLA: Can I ask Mike a question?

DR. MONSEES: Please.

MS. WILCOX-BUCHALLA: Is there some role that CRCBD could play in this? You may not be the absolute expert person to ask, but you're certainly a leader in that organization.

MR. MOBLEY: That's a good suggestion, and I'm chagrined that I didn't think about it, but yes. And if you could send me a draft announcement or something like that, I'll see that it gets in the newsletter. We could also have something at the annual meeting in May talking about the issue, too.

MS. WILCOX-BUCHALLA: I'm sure we'd be happy to provide somebody to go talk about the issue, since I'm usually there anyway.

MR. MOBLEY: Thanks. Yes.

DR. MONSEES: Do we have any other questions of Ms. Buchalla?

[No response.]

DR. MONSEES: Thank you very much--do you want to ask a question of Ms. Buchalla? Why don't you come to the microphone, please?

MS. DiPALERMO: DiPalermo, Siemens Medical Systems. I have a question concerning training of physicians, either surgeons or radiologists. Will there be provision for requirements for sites that become training sites, clinical training sites?

DR. MONSEES: This is a question to you, Ms. Buchalla.

MS. WILCOX-BUCHALLA: Thank you so much, Maria. There's no specific requirements for training sites with the exception of surgeons who have experience as trainers in stereotactic biopsy, and that is actually written into the joint agreement, that there is a pathway for a non-MQSA-qualified physician to do training in stereotactic. But that's the only specifics relative to training.

Does that answer your question?

MS. DiPALERMO: Is that public knowledge?

MS. WILCOX-BUCHALLA: Yes. That document has been published multiple times now, and it's out there.

DR. MONSEES: Thank you very much.

Before we come off of this subject, I'd like to just reiterate for the manufacturers in the audience: Please, you know who your customers are. You know who owns these units and where they are. We can only do so much. We would ask for your cooperation if you can communicate with your customers and let them know that they should

participate. Whether this is an update, whether this is on regular visits to the facilities, we would appreciate this, and this will help tremendously. Please, bring this back to your company and let them know that we're asking for your help in this collaborative effort.

Before we--go ahead.

DR. FINDER: I'd just like to make an announcement or a request. One of the purposes of the committee members is not only to bring this information but also to take information back to their constituents, and I refer this not only to the consumer reps but also to the people here who give lectures and speak at various meetings to emphasize this point. And I think that we can work from both sides, and I think the consumer demand for voluntary program accreditation would go a long way to help increase facility participation.

I also think that some of the people here not only give lectures before radiologists but also before surgeons, and, again, anytime that they can make a mention of this--and if you want to, you can use the Pizzutiello approach saying that the FDA is in the background and you don't want to see them too much. We would appreciate it.

DR. MONSEES: Now that we've also talked about interventional procedures a bit, I'd like to hear an update on what is happening with the regulation of units that are

used for breast needle localization and other interventional procedures that under the current regs do not need regulation but, in fact, I think the panel stated that we felt that that should move along. Can you tell us what's happening with that issue?

DR. FINDER: We've done some surveys and gotten some information about an estimate of the problem out there. I believe that you've been sent copies of the material that we've received. It appears that as far as we can tell, there's not a huge problem out there. There were reported a few cases of some problems, of minor problems, actually, in the performance of some of these studies.

FDA is still looking at the possibility, the likelihood of issuing regulation. We have in the works a notice of proposed regulation, which may be going out fairly soon, to begin this process. Again, we have to look at it in great detail. I don't want to say that we're putting it on the back burner because we really aren't, but right now our main energies are being focused on getting the final regulations implemented. We have until April to get all the various ducks lined up, if you want to use that term, because that's a deadline that is coming, April 28th. If facilities don't have the guidance, if they don't have all these other things in place, they won't know what to do, and under the law we have to do the inspections. We have to

make sure that they're meeting the requirements.

I think one of the issues which we've just come up with in the last few weeks is the business about the patient communication, which is necessitating rewriting the regulation regarding that, rewriting guidance, and at the same time getting out that information to facilities so that they can implement it. One of the things I'm not sure that was mentioned was the fact that the law actually goes into effect when it's signed. So certain portions of the reauthorization actually went into effect two weeks ago.

One of the things that was mentioned in the report from Congress was that they were giving facilities until the implementation date of the final regulations to implement the Patient Communication Act, a portion of the act. So what we have to do, in fact, one of our Mammography Matters was supposed to go out a couple of weeks ago. We had to hold that back and rewrite it to put in the front page that this is going to be a major change.

So we've been involved with trying to get the final regulations going, but this has not been forgotten, I can assure you of that, and we are moving ahead on that process.

DR. MONSEES: Where does the notice appear, the notice for proposed regulations? Is that in the Federal Register?

DR. FINDER: It would appear in the Federal Register.

DR. MONSEES: Thank you.

DR. SICKLES: Could you just inform the committee of the time line that would be involved, assuming that this becomes a front-burner issue? Just from when you begin doing it until when it is in force.

DR. FINDER: Okay. What you're talking about is going through the entire process, and it would involve the notice of proposed regulation, then coming up with regulation, proposed regulation, having that go out in the Federal Register and having that go out to the facilities, with usually a 90-day comment period. Then we'd come back, take a look at whatever comments we got. We would then publish a pro--not a proposed but a final regulation, which would then go into effect probably anywhere from a year to 18 months or so after the publication date. So it's not a quick process.

The other thing that one would assume is that it would have to come before this committee, at least in its various stages, probably before the proposal, then after, just like we did with the final regulations. So it would be an involved process.

DR. SICKLES: So we're talking at best a two- to three-year time frame?

DR. FINDER: I would think so, and that's, again, as we discussed at the previous meeting, one of the major reasons for going ahead with the voluntary programs.

The other thing you have to remember and take into account is the fact that this is still a new process for stereotactic. The voluntary programs are learning a lot, and what we would hope to do, if we do come out with regulation, is to take the information that they gained and incorporate it into the regulations. I think that without that basis, without their experience, just writing regulation could get us into a lot of problems because we might be requiring things that we find out later are not the correct way to go.

So it's a learning process all around, and we would hope that--again, we're encouraging the voluntary program as much as reasonable to accomplish the same thing quicker.

DR. MONSEES: When you asked the question, was it pertaining to stereotactic biopsy or other--

DR. SICKLES: No.

DR. MONSEES: That's the way I understood it, but I think the answer was the other. To review, the time line for that is the same process.

DR. FINDER: Still requires the proposal and everything--

DR. SICKLES: Yes, but the FDA has no plans to set up or even request some kind of voluntary accreditation of needle localization units.

DR. FINDER: That's correct.

DR. SICKLES: I mean, that was not the committee's intent in advising you initially. All the committee was asking was that the FDA simply make a dictum that they come under the auspices of MQSA as mammography devices.

DR. MONSEES: So it may not require additional--

DR. SICKLES: Could you simply make an administrative decision without having to go through the full regulation process that--

DR. FINDER: No.

DR. SICKLES: You can't? I don't know. I'm asking.

DR. FINDER: No. I mean, that would--no. That's a major change that would affect a large number of facilities. You cannot just--

DR. SICKLES: I thought you just said there are only a few facilities.

DR. FINDER: No, that had problems that we found out about. There were only a few problems.

DR. SICKLES: Do you have a sense for how many units are out there in the country being used solely for wire localization purposes? Because units that are used in

a dual fashion obviously are already covered under MQSA.

DR. FINDER: I believe that in the information that you were sent out, we got--

DR. SICKLES: I never got it.

DR. FINDER: You never got it?

DR. SICKLES: No.

DR. FINDER: Okay. We'll make sure that you do.

We did a survey in which we got responses from several states and a number of units that they felt--and, again, they don't keep records about this. But the number of units that were involved that they believe are being used for needle localizations that are not accredited, some states were, you know, like 20, 30, something like that. I believe that the largest number of units that was reported to us was in Florida, and that may have been as many as 100. I don't have the specific numbers off the top of my head, but I can get those to you and I will.

DR. MONSEES: Thank you. I fear as the final regs come along and the people are figuring what to do with their old equipment that they can't upgrade, they may be turning them for that use and that the numbers might increase. But it's something that's obviously just guesswork.

Yes?

DR. PIZZUTIELLO: If my memory serves correctly, when the MQSA first became effective in '94, there was sort

of a quick blip that came out that said that the division decided to temporarily exempt interventional procedures, primarily because there was no accreditation program, and that was not done without any--with any notice and comment and all that. Couldn't that decision just be reversed with the same streamlined process?

DR. FINDER: Well, I can't go into the specifics of how that was exempted, but I don't think it was just a fiat that FDA came--it had to be proposed, et cetera. Actually, maybe Mr. Showalter, who was involved in the process at the time, can go through that.

MR. SHOWALTER: Well, actually, it was done by fiat.

[Laughter.]

DR. FINDER: I stand corrected.

MR. SHOWALTER: However, it was done on September 30, 1994, which was the day before MQSA went into effect and facilities had to comply. It was done under the authority to do interim final regulations, and that authority, though, according to our counsel at the time, only extended to the initial implementation of the program. There were times when I tried to use that later on and was denied access to it. I don't believe that anyone would by sympathetic to the argument at this point that you could use interim final rules and go straight to a rule without notice and comment.

That wouldn't fly.

DR. MONSEES: Thank you for that.

DR. DEMPSEY: I think you can probably very quickly see the profile of instruments that are out there being used for that purpose, and that is, since the vast majority of mammography is done as an outpatient, those instruments are ones that are remaining in hospitals that really don't do volume mammography anymore to do the pre-operative needle locs. In other words, that is, one remaining instrument stays in the hospital only to be used for pre-operative needle locs rather than take the patient to the outpatient facility and then to the hospital. That's probably where they all are, I would surmise.

DR. MONSEES: Okay. Last comment here?

DR. PIZZUTIELLO: It might not be that simple to fold these units into the accreditation program. Just a reminder that the accreditation program was really based originally on a screening population, and these are very select populations who were used strictly for the needle locs. So getting the patients that fit the criteria to submit to accreditation and so on might not be as trivial as people think, so let's remember that when you work on the regs for that to look into that a little more closely.

DR. MONSEES: All right. A final comment. Then we'll move on.

DR. SICKLES: What Bob is relating to is that clinical image review would have to have different criteria because there won't be a volume of screening patients or diagnostic patients going through.

DR. FINDER: Right. It's a lot more complicated than just saying, you know, fold it in. But we are looking at the possibilities of doing that.

DR. MONSEES: Thank you. All right. Do you want to go ahead and talk about the next agenda item, review of summary minutes and future meetings.

Review of Summary Minutes of May 1998 Meeting

Future Meetings

DR. FINDER: Certainly. Does anybody have any question about the previous summary minutes?

[No response.]

DR. FINDER: Thank you. And now comes the hard part, the next meeting. I figure sometime next year would be nice.

DR. MONSEES: Do we want to do it before or after the final regs?

DR. FINDER: Well, after listening to some of the people talking about what they've got next year, I was thinking probably we could either do it much sooner than the final regulations go out, maybe in March, possibly April. But my preference would be to do it afterwards, and then

we're probably talking about June because I understand that May is a heavy month.

DR. MONSEES: So maybe people could get to you information about March and June?

DR. FINDER: Right, if they've got any dates that they know they can't make right now. If you'd just write them out, and what we'll do is the same thing we did before. We'll come up with some possibilities and fax them out to you. Then the other thing we have to do is try to get space for the next meeting. If you want, you can also come up with some suggestions about what you want to talk about.

Medical Records

DR. MONSEES: All right. We are now scheduled to continue our discussion of agenda items, and we have a break sometime this morning. If we could, just before we break, revisit the agenda item that we were discussing before we broke last night, and that was medical records. If you want to turn back to your draft compliance guide documents, which was pages 36 to 39 of the A document, 20 to 24 of the B document, and 25 of the small entity compliance guide.

Were there any other issues there? If you'll recall, we were discussing whether letters needed to go back out after addenda were made, and I'm not sure that we've come to closure on that, but I'm not sure that we can really quite practically come to closure on that right now.

Are there other items or are there any revolutionary suggestions about how we might--Dr. Sickles slept on it. Okay.

DR. SICKLES: Dr. Sickles has two proposals, but I think it would be very helpful to hear from other people as well.

My preference would be to have the FDA attempt, realizing that you may be constrained, to get your lawyers to somehow approve not requiring a second letter to the patient when the specific cause of the addendum is description that a clinician was notified of the results of the report. That would be the only exception. And it's very straightforward. It happens a lot, and I see no benefit to the patient to be notified of this specific fact.

On the other hand, I understand that you just may not be able to do that because of the way the regulation is written. If the regulation requires it, then I think the easiest way for facilities to comply would be to develop a highly streamlined letter to the patient that did not reiterate all the specifics of the initial letter which they had already received, but simply indicated that they're getting a second letter simply to notify them that their physician has been informed of the results.

DR. MONSEES: Okay. Any other items pertaining to the medical records, pages 36 to 39 of the A document, 20 to

24 of the B document, 25 of the compliance document? Any other issues that we want to raise about these draft documents? Ms. Hawkins?

MS. HAWKINS: In relationship to Dr. Sickles' comments is that notification of patient with the follow-up letters, this still remains a responsibility of a mammography facility to do that notification, does it not? Because I don't know if we would be able to depend upon primary care physicians or others to take on that responsibility.

Some of the more recent studies that I have seen, especially as they relate to older adults, indicate that they don't want to have less information about their care, but more information about what is happening to them. So I don't think that it's going to be as detrimental or as confusing to patients or consumers as you may think it would be to get those second letters.

DR. MONSEES: There are recognized responsibilities of the primary care physicians. This particular issue was looked at very carefully by the Agency for Health Care Policy and Research, and, in fact, those little fuchsia books--there's a set of them. There's a booklet for the practitioner, there's a booklet for facilities, and there's a booklet for patients. And there are very specific responsibilities that the practitioners need to be aware of.

That is, when they order a mammography, it's their responsibility to follow up with that patient about it. I don't think that all the responsibility needs to fall on the facility. The facility needs to participate, undoubtedly. But the practitioner cannot abdicate their responsibility. There are definite responsibilities, and I think those things should continue to be that way.

DR. SICKLES: The primary responsibility in a situation where there's an abnormal mammography result is with the clinician who ordered the test. That's where the primary responsibility lies.

As we sit here on a Mammography Quality Standards Committee, we have authority only over the facilities. They have a secondary responsibility. So what we're doing is we're addressing the facilities who have secondary responsibility, realizing that the primary responsibility really lies elsewhere.

When you get a mammography done and your doctor gets the report, your doctor should be calling you, and in most circumstances, of course, your doctor does. The purpose of patient notification is simply--among other things, it's to avoid a situation where the primary responsibility of your doctor just doesn't take place. And as we know, that happens occasionally, so this is a fail-safe to overcome that possibility.

DR. MONSEES: The document that I'm referring to is called "Quality Determinants of Mammography." It's published as three separate documents that go together--one for the patient, one for the referring physician, and one for the facility. "Quality Determinants of Mammography" by the Agency for Health Care Policy and Research. Is there any more information about how to get that document, do you know?

DR. FINDER: There's 800 numbers you can call to get it if you want that.

DR. MONSEES: You might want to get a copy of that. "Quality Determinants of Mammography." It's a few years old, but it's really quite current.

Any other issues pertaining to medical records that we want to talk about on this panel, those pages?

DR. NISHIKAWA: Charlie can veto this question right off the bat if necessary. It's the small document, page 23 at the bottom, mammographic image identification. We now have a digital system which, as far as I know, we are not printing onto hard copy. So they're going to be reviewed only from a monitor, in which case we can't physically place--well, we could, but right now the way the system works, there's no identification in the image that appears on the monitor. Could that be confined in this regulation or not? Is this regulation not applicable?

DR. MONSEES: And fold that into a bigger question. Since some of these units are being placed in the country, what are we going to do when digital mammography is out in practice? And it's about to happen in some facilities.

DR. FINDER: Okay. First of all, at this point, digital is still an experimental or investigational tool, so it doesn't have to meet any of the requirements.

The broader issue that you bring up is the issue about when the new technology comes into the mainstream and has to be accredited and certified, and whether these things will apply in some manner to the various aspects of the new technology.

In certain areas, we've already made the statement in the final regulations that they have to meet what the manufacturer specifies, mainly of the QA and QC. I believe in terms of mammographic identification, there would have to be some method to meet the requirement. The question is there would have to be new guidance probably related, and we'd have to look at the specific systems. And until they become available, it's going to be difficult to do that. We are working with manufacturers as these things come up, and the issue about soft copy interpretation of digital mammography is being discussed. So before these things become commercially available in terms of being accredited

and certified, these issues will have to be defined and worked out.

DR. NISHIKAWA: Are those issues brought up as companies goes for FDA approval? Do you check to see whether they're in compliance?

DR. FINDER: Yes.

DR. SICKLES: As a user of one of the investigational digital units, and particularly since we look at our images only soft copy, I wouldn't go too rapidly down the line of not requiring labeling on the images. It is certainly feasible and I think very important to have almost all of the labeling that is on a film mammogram on the digital image. You want the patient's name. You want the date of exam. Really, the only thing that serves no purpose is the facility name and address, because if you're looking at a soft copy, you know where you are.

DR. FINDER: One other thing. I think that cassette and screen identification--you know, these wouldn't apply.

DR. SICKLES: Yes, cassette and screen identification wouldn't apply, but if you have more than one digital unit, the room would apply.

DR. MONSEES: All right. Let's stop this here because what we're getting into here is discussion of what we can eventually talk about, I guess, if digital regs need

to be developed.

We're going to go to a break now, and because of checkout time, et cetera, let's discuss--the original agenda said we were going to go to lunch from 12:00 to 1:15, but checkout time I guess is about 12:00. So we're going to go to break now for 15 minutes. Then we'll reassemble, and then you can count on the lunch beginning at 11:45 at the latest so that there will be checkout time at that opportunity. Okay? Any other things that we need to do before we go to break?

DR. FINDER: I would also like to raise the potential of it might pay to work through lunch if we can finish early, and maybe you would want to check out now for that possibility. It depends on how the rest of the day goes.

DR. MONSEES: Okay. He's suggesting that, if possible, we could get through the rest of the agenda items and, therefore, work through lunch and then get out earlier. I think that sounds very attractive, although I don't want to rush the discussion. I think we need to give it fair discussion. So we may still have to break for lunch, but those of you who want to consider working through lunch and you need to check out, you may want to do it now.

So we will do a 15-minute--let's give it a 20-minute break then so that we have time to check out if we

want to. Reassemble in 20 minutes.

[Recess.]

DR. MONSEES: We'll reconvene now. We're going to begin with medical outcomes audit. Before we do, I just want to revisit medical records for just a second. Somebody from the audience asked about this, and I think this is an important point.

On page 22 of the new document--where is it?

Question: When a facility ceases operation and closes its doors, what should it do? And that's on page 22 of the B document. And we were hearing that, for example, in the State of California, when a facility closed, it was hard to get the films relocated to a new site, and there was concern over those films being basically lost to the patient in terms of availability.

One of the things that I was thinking was that they should be available to the patient. Actually, that's included in the comment to that. So if you would just look at that and see if there's any other guidance that we could give the FDA about what might happen with those films. It looks like it says to make arrangements to transfer each patient's medical record, original mammography films, and reports to the mammography facility where the patient will be receiving future care and the patient's referring physician or the patient herself. So maybe it should be

emphasized that if any of the others are unknown, a letter should be sent to the patient herself so she can pick up her films and be responsible for those. Especially with what Mr. McCrohan was talking about with patients having access to their records, I think that would be a pertinent addition.

Medical Outcomes Audit Program

DR. MONSEES: Now we're going to move to medical outcomes audit, pages 57 to 60 of the A document, 35 of the B document, and it happens to be on 35 of the small entity compliance guide as well.

Do we have any suggestions for the FDA for their guidance here?

DR. SICKLES: While you're looking at yours, I can start with mine. Why don't we do A first of the big document first? If you go to page 58, that first question on the top, you know, where can a facility obtain more information about medical outcomes audit programs, since you are quoting the AHCPR document and Mammography Matters, you might also wish to cite the new BI-RADS third edition which has an excellent updated and--what represents the most current section on auditing.

DR. MONSEES: That was going to be one of my suggestions, too. It's very complete, and it gives not only detailed information about a detailed audit but more

streamlined audits as well.

DR. SICKLES: It gives information on how to do two audits, and there's even sort of a cookbook form as to how to do the calculations. It's very convenient. So you might want to cite that.

DR. MONSEES: Can we do that?

DR. SICKLES: If you can.

DR. FINDER: I'd have to check into that. The things that are cited here are federal documents, so I'd have to check and see whether we can refer to specific manuals like that.

DR. SICKLES: If you can, that's the best source.

The next one is at the bottom of the page, the question at the bottom about confidentiality. The response is, to my reading, less than convincing by saying FDA does not intend to have inspectors obtain copies. I think it would be a lot more convincing, if you really meant it, to say FDA will not permit inspectors to obtain copies. That would be a much more convincing statement, if it's true. Because if you just say FDA doesn't intend to have them do it, then, you know, of course, they could still do it. If they're really not supposed to do it and you don't want them to do it, then you could use stronger language.

DR. FINDER: I think that the reason it was written this way is, again, we're not trying to limit

ourselves in terms of what we can get, and this may be in conflict with the other portion of the Additional Mammography Review when we have to go and collect information for that. So, again, during the routine inspection, that would not be an issue, but I don't want to put in here something that--we'd have to check and make sure that it wouldn't be in conflict with the AMR policy, and we don't want to do that.

DR. SICKLES: Okay. Do you want me to continue, Barbara?

DR. MONSEES: Sure. I had a comment on this page, too.

DR. SICKLES: Why don't we do yours? I'm up to the next page.

DR. MONSEES: Maybe you've already seen it some other place, but up above, the general requirements, which mammograms must be included in a medical outcomes audit system, because of the confusion yesterday that we discussed about the incompletes, and it says here that you need to do the follow-up of the suspicious or highly suggestive, I think that we need to say that the incompletes need to be resolved, and any that fall into this category in the final assessment should be included in that. But I think we need to have some statement that the incompletes need to be brought to resolution. Don't you feel the same way about

that?

DR. SICKLES: Obviously the incompletes need to be brought to resolution, but the incompletes won't fit into this specific definition, until they are brought to resolution and they become BI-RADS 4 or 5.

DR. MONSEES: Right.

DR. SICKLES: But we can be very explicit.

DR. MONSEES: But since most of the final assessments start as incompletes and end up as 4 or 5's, I don't want it to be left out that the incompletes need to be brought to resolution to determine if they're 4's or 5's.

DR. SICKLES: Yes. Perhaps Dr. Finder wants to address the issue that we discussed off the cuff yesterday.

DR. FINDER: The issue comes up--the regulation requires that all the suspicious and highly suggestive be included. The issue that can come up in certain situation is take, for example, the screening facility that decides or as policy does not give a diagnosis of suspicious or highly suggestive of malignancy, but puts down incomplete for further workup. That may not be the facility that does the workup, in which case all they will have are the incompletes.

If we're talking about making them do follow-ups on all those incompletes, then we're changing the requirements. So we have to be very careful. I mean, we

can suggest in the guidance things, but we have to be careful about what can be required. I certainly have no problem including something about the incompletes and how they might be handled under certain circumstances until we can--

DR. SICKLES: Clearly there might be a specific circumstance--and I don't think it will come up frequently, if ever, but there might be a circumstance where a screening-only facility which is relatively low volume might actually go through a year where all of their recalls are actually classed as incomplete and none of them are classed as suspicious, so they won't have a lot of data.

I don't know if you can do this or not. I don't know what the regulations permit you to do. But it might be helpful to have a statement strongly discouraging facilities from using incomplete in the diagnostic mammography sense. I mean, that certainly builds into BI-RADS. I don't think you can prohibit it, but you can certainly discourage it.

DR. MONSEES: Dr. Dempsey?

DR. DEMPSEY: I would just like to briefly revisit Dr. Sickles' first comment so that Dr. Finder can be aware of the importance of this patient confidentiality issue.

At our facility it's probably the only issue where employees will be dismissed summarily for violation of anything along those lines, and I think that Ed's reticence

about the somewhat mild wording of that guidance needs to be addressed, because it is a very big issue.

DR. MONSEES: Okay? Yes, go ahead.

DR. SICKLES: Okay. If you will go to page 59, right on the top, this actually relates to something that's suggested--and I'm asking a question rather than making a specific change. If you read through the timings of what's listed there about the facility's first audit--and that's under the final regulations--what I'm reading through this is that a facility cannot be cited for a new regulation audit violation until April '01 because it takes a year before it goes into effect, then you have a year to collect the data, so that would be two years after April '99, if that's correct. And the only thing that you might--if that's true, which I assume it's true, what you might want to do is state that clearly but also remind facilities that those which are already in operation still will have to produce audit data under the interim regulations up until April '01. I assume they will; otherwise, they won't have to do any auditing between '99 and '01.

DR. FINDER: Yes, I think that what we're talking about here--

DR. SICKLES: Because the audit is slightly more extensive under the new regulations than the old regulations, you may want to make it clear that you still

have to follow the old system up until this time, and then the new system kicks in as of so-and-so.

DR. FINDER: I think that's a good point. This is referring to the specific point of frequency of analysis, but obviously they have to continue to do the audit as they have been doing under the interim regs, and we can put some clarification there about that.

DR. MONSEES: Are there any other comments, Dr. Sickles?

DR. SICKLES: I have one more, but this is on B, the shorter document, and this is on page 35. Again, this is a question. I'm not sure whether this is specifically addressed in regulation or is just part of the language of the regulation. But right on top of the page, the 21 CFR thing in italics, the last sentence of that talks about how the facility should initiated follow-up on surgical and/or pathology results in review of mammograms if you become aware that there's a malignancy involved.

Does this actually generate additional--I mean, I'm not aware that inspectors are looking for anything other than the usual correlation of abnormal results with pathology results. Is there intent here that there be more than that or that any cases of known malignancy simply get folded into that type of reporting?

DR. FINDER: It would be the latter, that those

cases that become known become part of the audit.

DR. SICKLES: Whether you call it abnormal or not, in other words.

DR. FINDER: Right, but you can--

DR. SICKLES: If you become aware of a false negative, it really ought to be in there.

DR. FINDER: Right.

DR. SICKLES: Again, if that's the situation, as I believe it to be, you might want to make it a little bit more explicit, maybe not in this section because there's no question about it, but in the question later on where--or maybe it's in A where you're talking about what gets included in the audit data, and you talk about, you know, if you interpret it as BI-RADS 4 or 5 it does. You might add a sentence saying that also if you become aware of a false negative, it ought to be put in there, folded in. Okay?

DR. MONSEES: Also on that page, the first question is: Must facilities differentiate screening from diagnostic studies when analyzing their medical outcomes audit data? The answer is: No. Although facilities must include all positive mammograms in the audit, they're not required to perform separate analyses for screening and diagnostic exams.

I think I'd like to see in there a statement saying that it is preferable to separate them. Although

it's not required, it is a helpful analysis. And, in fact, in order to be able to compare your data and your track record to published standards, it is helpful to separate them out. You cannot compare a combined database because of selection bias, high-risk patients that might appear in there, et cetera. You can't compare that data to anybody else's. But if you have a pure population of screening patients, you can compare it and you will get a feeling for how you're doing in your track record. So I think it should be encouraged, although not necessarily required. I'd like to see that comment in there.

Yes?

DR. DEMPSEY: I'm glad you made that comment. I was going to make a similar comment based on another aspect of it, and that is, without separating the screening and diagnostic, your review of your radiologists and their reading capabilities is almost meaningless. Because if Radiologist B did nothing but diagnostic problems and no screens, you wouldn't have an idea of his or her sensitivity.

DR. MONSEES: Absolutely.

DR. DEMPSEY: So it bears on it from another aspect as well.

DR. MONSEES: Absolutely. Yes?

DR. SICKLES: Just to further that comment,

although I don't know that you really want to put it in the guidance, but as a practical matter, in most practices which will be collecting data on an annual basis, once you start breaking down results by radiologist, you're going to be dealing with very, very small numbers of cancers per radiologist per year. And the analysis of this data becomes subject to large statistical variation. One year the radiologist may find none, and the next year he may find five, and that doesn't indicate that he had a good year and a bad year. It's just statistically how many women with cancer came through his reading lab or her reading lab.

DR. MONSEES: Does it stipulate in here that the audit information is also confidential and that you don't have to give it or show it to the inspector, just that you've done it? Because I think that many radiologists are concerned about that, especially with the medical-legal implications and discovery, et cetera. Is that stipulated in here? I don't remember seeing it.

DR. SICKLES: That you don't have to show it to the inspector?

DR. MONSEES: Well--

DR. SICKLES: I don't think that's stated.

DR. FINDER: That's actually an interesting question. What do they have to show? Is it okay to accept somebody's word that they do it, or do they have to see

something to show that it's actually been done? And, again, the idea here is that nobody's going to be taking this material and, you know, making copies of it and taking it away. However, I think that it is reasonable to ask--or in some cases to have the inspector take a look and say, yes, there actually are these files around, not that they look at each individual patient, but the alternative to that is just to say, oh, yes, we do it, it's in our SOP. And that's not what we've been doing actually under the interim regs. They have been going in and taking a look to see that there are lists. Again, they don't look at the individuals, but to make sure that the material actually is there.

So I don't want to get too involved with this in terms of the guidance because, yes, they will be looking at this material, and I don't want to give the impression that they necessarily don't.

DR. MONSEES: Can we make sure that it's stipulated that it is confidential and that it is not accessible via the Freedom of Information Act? Because people are interested in the fact that it's not discoverable. It should not be--internal audit data should not be discoverable, and I don't think that people want this to be entree for that to happen.

DR. FINDER: And, again, that was discussed extensively with the committee, and that's why we did not

ask for specific data to be obtained and we don't collect specific data. And the issue of if an inspector sees that there's a list of material there, that's not FOIable in the sense he doesn't have any data, he doesn't take anything with him.

DR. MONSEES: Great.

Any other comments pertaining to the audit?

[No response.]

Consumer Complaint Mechanism

DR. MONSEES: Okay. Let's move on to consumer complaint mechanism, pages 63 to 64 in the A document, 36 to 37 in the B document, and 36 in the small entity compliance guide.

Do we have any comment on the draft document given to us, the draft documents given to us?

[No response.]

DR. MONSEES: I'll turn to our consumer reps and anybody else who feels that they'd like to make a comment.

MS. BROWN-DAVIS: My comments are on page 37 of Document B. I was a bit disturbed by my understanding of this. I'll start with paragraph 4, I guess that's line 1404 to 1406, in response to the individuals filing the complaint within a reasonable time frame. I had no idea--and I'll make a comment on all of this afterwards. I had no idea what 5 meant. They design their complaint procedures to be

responsible to the particular needs of the patients they serve. I don't know what that means.

Then line 1415 to 1416, the facility reports unresolved serious complaints to its accreditation body in a manner and time frame specified by the body. So, again, it looks to me that the consumer is not really given anything specific to expect. The accreditation body gets to specify the time frame in which they get the information. The consumer gets to wait and get responded to within a reasonable time frame, which I think is just too loose.

DR. MONSEES: Okay. The accrediting body, the major one, the ACR, do you want to comment, Pam? Aren't you the AB here? You do have a copy of B documents, don't you? The facility reports unresolved serious complaints to its accreditation body in a manner and time frame specified by the body. Do you have a manner and time frame that's specified, or are you working on that?

MS. WILCOX-BUCHALLA: We will be working on it. Since this guidance is relatively new, we'll be working on developing recommendations to facilities. But I think it is important for us as the AB to hear what the consumer reps think is a reasonable option.

DR. MONSEES: Okay. So that's good. Let's hear. What do we think is reasonable?

MS. BROWN-DAVIS: I think that we can use as an

example the State of California. They seem to set a 30-day guideline or 30-day time frame to get back to the consumer, if I understood what was presented yesterday. Is that correct?

DR. MONSEES: Is Patricia Edgerton still here? Is it 30 days?

MS. EDGERTON: Yes.

DR. MONSEES: Thirty days, she says. Okay. So that's--does that seem reasonable?

MS. BROWN-DAVIS: Well, yes. I mean, you know, there's an end.

DR. MONSEES: Right, 30 days, sounds like most people can accommodate in 30 days. Okay. So there's your suggestion. Everybody here seems to think that's reasonable. Okay.

Now, pertaining to 4 and 5, those other parts that you weren't sure you understood?

MS. BROWN-DAVIS: Right.

DR. MONSEES: Number 4, let's do that one first. That one--what was the--the facility investigates the complaint, makes their effort to resolve the complaint, and responds to the individual filing the complaint within a reasonable time frame. Was it only the time that was the problem with paragraph 4?

MS. BROWN-DAVIS: Yes.

DR. MONSEES: Okay. So that's been addressed. Number 5, I think you said you weren't sure what it meant. After you said that, I'm reading it trying to figure out what it meant, too.

MS. BROWN-DAVIS: It sounds like a filler to me.

DR. MONSEES: Dr. Finder?

DR. FINDER: Well, it's not a filler. Basically this was to take into account the fact that facilities may be dealing with certain populations that have to have specifically different consumer complaint mechanisms, language, customs. They have to try and establish a system that is appropriate for the patients that they're going to be dealing with. For example, one size does not fit all, and that's what this is supposed to be in the sense that, you know, a facility might have to have, in effect, two different types of consumer complaint mechanisms to deal with the various populations that they have to serve. That's what it was supposed to address.

DR. MONSEES: Could you come up with a better wording, do you think, in here?

MS. BROWN-DAVIS: Well, I think that taking care of--because, you know, I mean, I think that the fact that a 30-day time frame is rather long, it could be shorter if there were no language barriers or this kind of thing, that perhaps--I'm not even sure it even has to be in there

because it would seem to me that the onset would be 30 days. If something could be done sooner than that, it would be. And so that--do you understand what I'm saying? Those situations in which there was a language barrier or some reason that this population could not be handled quicker than 30 days?

DR. FINDER: Oh, I'm not talking about that.

DR. MONSEES: I think he's trying to--maybe paraphrase it is to say that the facility should be sensitive to diversity in language and cultural differences that may affect a patient's access or understanding of the repercussions the facility might have, or, you know, that they do have recourse and that they can complain. So I think that's what it means, isn't it?

DR. FINDER: Right.

DR. MONSEES: That's what it's intended to mean.

DR. FINDER: Yes. To my way of thinking, the two are separate. But the reasonable time frame would apply to everybody, whatever that time frame is, and, you know, 30 days, if that's what accreditation body said, I think that would be reasonable.

The other is separate from that, and whether you have a different type of system for your individual patient populations, it would still have to be within that same time frame. So I don't think that--

DR. MONSEES: Right. We're not going to alter the time frame, but how should we tell the facilities and change the wording of 5 to say that they need to be sensitive to those issues?

You deal with a lot of different populations, Dr. Sickles. How could we tell them?

DR. SICKLES: Well, I think in this language you can just add a sentence explaining what you mean there, because the sentence as written doesn't really achieve the goal that you intended. It's very vague and it could be made a little bit more specific.

DR. FINDER: I would certainly be open, before everybody leaves today, if they've got a suggestion, you know, to include that. I would certainly take--we don't have to discuss it right this second.

DR. MONSEES: Okay.

DR. FINDER: Unless somebody's got an answer or a suggestion.

DR. MONSEES: Yes, Ms. Hawkins?

MS. HAWKINS: I think, though, in addressing that statement, that it be responsive to the particular needs of the patients, is that patients should be allowed to complain in person as well as in writing, because I think that may create a situation with the process of complaining.

DR. MONSEES: And I think that's especially

important considering some people are illiterate. So that is important.

MS. HAWKINS: I was going to address another issue. The issue that I would like to look at is that since the consumer complaint mechanism is going to be one that the advocacy groups are going to be working with as a way to improve mammography services and so forth, in looking at the question--and I'm in the large document on page 63, How is a serious complaint defined? I think that there should be some additional examples here so that advocacy groups will know what to instruct consumers to look for, because, you know, much of what we're defining as a serious problem, you know, has to do with poor image quality, the use of personnel that do not meet requirements in the statute and so forth like that. And these are things that--these are issues that are going to come out of surveys, inspection surveys.

As we heard in our last meeting, many of these survey reports are not going to get to the public. It's going to be a sizable amount of time, because I remember at the last meeting you said perhaps about three years.

So I think that rather than the issue focus on process, most consumers are going to be focusing on outcome. And I notice that when we looked at the Additional Mammography Review, one of the areas of defining a serious

complaint was missed cancers. And I think consumers may understand that, is that they feel, you know, they had a mammogram done, and then at a later date they were discovered, they feel that the cancer was discovered and we're looking at the false negatives. I think that this is something that they would be able to understand, would be missed mammograms.

I think also the issue of repeats, you know, frequent repeats or incompletes or call-backs, and so forth, that these are things that consumer groups would be able to convey to a consumer group, that these are the kinds of issues we need to bring to the attention of FDA.

DR. MONSEES: Is this the proper forum to go through the list of all of the possible complaints? Is there some other forum that consumer groups would have access to? You know, what's the role of this draft guidance document pertaining to all of the different possible complaints?

DR. FINDER: Well, I would say we can't include all the possible complaints, but certainly examples that the group thinks are representative of what the consumer out there is going to run into, I don't see any reason why not to include it; because, again, this document is not only for the facilities, it will also be available to the general public. So it's up to what you want to consider.

DR. MONSEES: I have some concern over using a missed cancer as a serious complaint because I think in some circumstances it is a problem with the mammogram or the interpretation, but in many circumstances it's not. I mean, that's just par for the course.

Would you like to comment on that?

DR. MENDELSON: I share your concern there. There are interval cancers, and the FDA's MQSA is not a tribunal, and it's not a medical authority on whether something was diagnosed at an appropriate time, whether a threshold for diagnosis had been exceeded or any other thing. I think perhaps other better examples might be with respect to diagnosis of cancers. Perhaps a woman who called a facility where she had gone before with a problem, something that she may have felt and was told that she couldn't have an appointment for a month, something of that sort may be something more appropriate to record among these kinds of complaints.

I also do think that in the definition of what a serious complaint is should be included examples of what serious complaints are not, such as calling on the telephone and not having the phone call picked up until the 14th or 15th ring. That's not serious. But it would be something of concern if a facility had been phoned for an appointment and the patient not given one for an extended period of

time, even avowing that there was a problem, something of that sort. But to have both in the guidance, both what is appropriate for a serious complaint and also examples of what are not serious complaints.

DR. MONSEES: Okay. Yes, maybe--I don't know whether this is important--to define serious two different ways, but I think it's very important to do that, because what a consumer might think is serious might not mean that it results in their detriment of their health, which I think is what--the word serious here is being used it could compromise their health. And I think that that needs to be understood. It doesn't mean that it just seems serious to the patient.

I'll let Dr. Sickles speak, and then I'll get back to you, Ms. Hawkins.

DR. SICKLES: I have serious, actually very serious reservations about considering missed cancers as a consumer complaint issue. The reasons are medical-legal. Facilities, I can almost guarantee the FDA, are not going to want to be put in a position of having to respond in writing in any way to a consumer who approaches the facility with a missed cancer query without going through a lawyer. They won't. And you know that.

So to build it into the consumer complaint mechanism will basically be--will complicate the ability of

a facility to respond in a timely way because they're going to go to their lawyers, and then the lawyers are going to draft some statement that doesn't--it won't really be that responsive to the woman because once lawyers get involved in these things, nothing is responsive.

That doesn't mean that it isn't an important complaint, but I don't think it should be in a venue where the lawyers are going to take over because then we no longer have the meaningful dialogue that is what we really want.

DR. MONSEES: Lawyers aside, the other reason that I thought that it was important is that I don't think that the expectation should be that if a cancer is missed that it means there was anybody at fault and that there was a problem.

DR. SICKLES: Right. Apart from that--

DR. MONSEES: People's expectations are already high. Mammography is a very good technique, but everybody knows that it's not perfect, and there will be cancers that are missed. And I don't want people to think and I don't want to foster the opinion that if a cancer is missed, somebody was at fault. I don't believe that we want to be in the position to foster that opinion.

DR. SICKLES: I agree with you.

MS. HAWKINS: And that's as I say, but one of the reasons I felt comfortable in using it is that the

terminology is used in the Additional Mammography Review, is that on page 11 of this document where it says, you know, Level 1 findings, when we ask for additional review, and it comes out, the proportion of it, is that where the AB or FDA has received serious complaints about the quality of the physician's interpretations, accuracy, that is, missed cancers, incorrect interpretations, and so forth. So it's used there, and I don't see why it cannot be used in the context of informing a consumer.

Now, when we look in terms of serious complaints, we're looking in terms of complaints that are going to be fully investigated. And so it's not that a consumer is just going to be able to go out there and say, well, they missed my cancer, close them down, take them to court. But the actuality is that some cancers are missed. And there are, indeed, you know, inaccurate interpretations and so forth. We talked yesterday about, you know, when physicians are-- interpreting physicians have to go under supervision, that this appears to be something that occurs. You know, I don't think it's unreasonable to ask that that be one of the ways of listing this. How else can consumers know?

And even though I know that this whole process is intended to improve and assure me as a woman that I can get a good mammogram, but there is no way that I as an individual can go into a mammography facility and come out

and know that I have had a good mammogram. There is no way I can see that. You know, there are no visible signs. The person may have that there, but, you know, as far as what goes on, it's got to be entrusted to the process.

DR. MONSEES: Would you like to respond to that, anybody? Yes?

MS. WILSON: I was wondering if the intent of this was to have serious complaints driven by the topics that are covered under MQSA regulations.

DR. MONSEES: Dr. Finder?

DR. FINDER: Well, first of all, there is a definition for serious complaints, actually for all these terms, in the definition section. And I think that obviously the complaints are--in the final regulations.

The other issue that you bring up, are these serious complaints that are under the auspices of MQSA, and the answer to that is yes. MQSA, though, covers a tremendous amount of ground in terms of mammography, and it does include in some of its sections specific reference to interpretation, accuracy, those kinds of issues. So I think that we can certainly look and see what we can do about modifying the language to include more examples.

I've heard many comments from both sides about some of the pitfalls of doing something like that, and we're going to have to look at that. But I think that we can

certainly look at all the examples that were brought up and see what we can include.

DR. MONSEES: Okay. Just let me give you the definition in the small entity compliance guide for serious adverse event. A serious complaint is one that leads to--is defined as a report of a serious adverse event; an adverse event may significantly compromise clinical outcomes--that may significantly compromise clinical outcomes, or an adverse event for which a facility fails to take appropriate corrective action in a timely manner. So any of the MQSA regs that corrective action, which is stipulated for most of the final regs, what is the time, the permissible time for corrective action. If you don't do that, that could be a serious complaint.

Yes?

DR. SICKLES: I don't mean to be misunderstood by what I said before. In truth, cancer not detected at mammography is an adverse clinical outcome. It is. The problem that I see is in forcing the consumer complaint mechanism to address that adverse outcome. I don't think that's the best way to address it, except perhaps to let the FDA know when these happen that they're occurring, because if the FDA gets 12 of them from one facility, then it may indicate a pattern that the FDA wants to go after. And for that purpose, I think there may be some value. There's

actually some value to the facility as well because one of the things facilities have a hard time doing is identifying their own false negatives.

The consumers may not appreciate this, but facilities have an easy way to find out about their true positives. When they call it abnormal and it's cancer, we track those. But we don't track the negative cases, and we only find out about false negatives when somebody tells us, or if the woman were to come back next year and, you know, we read it as normal and all of a sudden we notice that she's had a breast cancer operation. So facilities do need to have ways to identify false negatives, and this is one way in which a facility may find out.

I just don't want to get in a situation where the FDA is caught in the middle of medical-legal problems, and you may want to consult your lawyers before you work out the wording of this.

DR. MONSEES: Needless to say, obviously, a missed cancer may, in fact, be the mechanism to highlight a facility that's a poor facility. On the other hand, it may just draw attention to a facility that's doing a good job because there are, unfortunately, all too many missed cancers, no fault of anybody. That's just the way--unfortunately, mammography has its limits.

MS. HAWKINS: If I might just say something else,

one of the reasons why I think that it is an issue that consumers need to be aware of is because of the fact that there is no tracking false negatives. And somehow--but it's a big issue because we still have--even though, you know, mammography, the system is doing a great job, but we still have far, far too many women who will die of breast cancer. And so I just think it's an issue from a consumer perspective, and especially since we have many of those issues that relate to disparities in how health care is delivered. When we think in terms of these disparities that exist out there among minority groups and the general population, we know that many of them are due to what happens within health care facilities and so forth.

You know, there have been a number of studies that have looked at treatment of heart disease and follow-up and so forth. Even, too, when we think in terms of what's happening with the issue that I raised this morning about responsibility for reporting, we have a number of studies that show that minority women as far as follow-up after an abnormal mammogram is longer than it is for other women. So we need to have these answers.

So I think it's very important that we go out there, because the only way we can improve this is improve what consumers know about this process and improve their participation in it. And improvement means being very

honest with consumers.

DR. MONSEES: Right. And we have a long way to go, and a lot of it has to do with prior to all of this, and that is that people need to know and their doctors need to know that they need to get mammograms. And a lot of the death rate in this country, unfortunately, comes from the fact that people, despite all that's been done, despite all that's been said, are not going for mammograms at the rate that they should. And a lot of the disparity between different groups in terms of death rate has to do with compliance with screening guidelines and recommendations and access to care, not necessarily even beginning to talk about women that are in the system and that are getting mammograms. So that happens. We won't impact those underserved populations. They need to get in in the first place. And, of course, that's all I'm going to say because we're talking about mammography here, not talking about how to get people in for mammography.

Yes?

DR. MENDELSON: A couple of comments. I think we all share your concern, and one of the ways that I think we identified some years ago that would be effective in dealing with this is making patients, consumers, women, interactive with the health process. Their education is something that I think we have all been committed to, and I think this

entire discussion for the last two days really has grown out of an increased awareness on everyone's part of what we can attain, what we can achieve, that it does have some limitations, that there are some outliers on either end, and that we need to address it together.

So the interactivity is one of the things that I think, as we focus on this consumer complaint mechanism, that just brings me to really--I think that is important. The education part of it is something that I think we all need to share in the responsibility to achieve. But the consumer complaint mechanism isn't the final pathway. It's one way to go. It's not the way to seek satisfaction altogether. And it's incomplete as we see it here that it's left to facilities. What do you complain about? To whom? What's done about a complaint? Is there a written response? Is there a telephone response? Is it the medical director of the facility? Is the supervisory technologist? Who is responsible for responding to these complaints?

And then ultimately the FDA can be sought as an arbiter if there is no satisfaction. What will the FDA do and who will provide that satisfaction? That is a question here that I'm left with reading the consumer complaint mechanism.

DR. MONSEES: Yes?

DR. SICKLES: I have a different issue if we're

finished with this one. I don't want to close out the discussion on this unless we're finished.

DR. MONSEES: Do you have any last comments on that, on this issue before we move on? The same thing, consumer complaint mechanism, he's going to discuss. But on what we've just been discussing, do you have any other--

MS. HAWKINS: No, other than to say that we are, indeed, talking about a Level 1. We're talking about serious complaints, and consumers cannot be left out of this process. I don't think it's beyond what a consumer should have to deal with or be part of that process. I think it's very important.

DR. MONSEES: Okay.

DR. SICKLES: The other thing I want to direct your attention to is on page 37 of the B document, and it just has to do with the wording in the text. I think there's probably a way around this.

If you look at line 1408, number 5, facility encourages complaint reporting by ensuring confidentiality of their patients, this could be--I'm not sure that the word confidentiality--the use of the word confidentiality here seems to contradict what is on line 1398, which is that all consumer complaints require recordkeeping that include the name, address, and telephone number of the person making the complaint.

You know, either what your intent is is that the facility that is maintaining these lists has to keep the list under lock and key or some other mechanism, and then that ought to be explained on line 1408--and I suspect that's what you mean--or you've got to change the word confidentiality on 1408 so that it doesn't seem to contradict what was above. Obviously facilities should maintain a list of who is complaining and how to get hold of those people because they need to do that in order to address the complaint properly. And if there's ever going to be an investigation later on of them, the investigator has to know who complained. But I think it could be a little bit more explicit here so as not to see self-contradictory.

DR. MONSEES: Do you think along these lines, thinking of a facility where, of course, where we have our share of people that call and have complaints, that we can share our concerns with the primary care physician? Often there are people that can't get appointments or whatever. You can imagine that they may have been talked to in a fashion that they might consider rude or whatever, or their doctor didn't get a copy of the report. Can we share--in terms of confidentiality, does that mean that we can call the physician and speak with them about these things? Would that preclude speaking with the physician?

DR. FINDER: You're asking a legal opinion?

DR. MONSEES: Well, I don't know. Now that he's bringing this up, I--

DR. FINDER: We can look into that and find out whether that's allowed or not or a good procedure or not. We can, again, give some recommendations in the guidance, but at this point, I just don't know the answer to that question.

DR. SICKLES: As a practical matter, in resolving a complaint, one of the things that one might do is actually speak to the person who's making it. That's the way we resolve our complaints. We call them up and say, you know, explain exactly what's going on.

DR. MONSEES: We do, too.

DR. SICKLES: If part of the complaint could be transmitted to, for example, the referring physician, it's very simple to just ask the woman who's complaining, Would you mind if I share this with your doctor? It might be helpful. And if she says sure, then there's no problem at all.

DR. MONSEES: Oftentimes, in terms of making appointments or finding out about follow-ups, et cetera, it comes into play. So that's a good suggestion.

Yes?

DR. DEMPSEY: As Director of Radiology in our

outpatient facility, I am involved in all consumer complaints in every aspect of our department, and I can tell you that communication with the patient's referring physician is quite key in making sure that everybody understands what's going on. And it is not a breach of confidentiality because that is the patient's referring physician, and as the result of that physician ordering the test, this somehow transpired and so it's all part of a reporting mechanism. So it's quite official, and I think part of resolving these complaints is to get the primary physician involved, because many times in investigating the complaint, what they really wanted in the first place is key to find out if something was transmitted correctly.

DR. MONSEES: I agree with you.

Okay. Any other issues pertaining to the consumer complaint mechanism, pages 60 through 65 of the A dc, 36 and 37 of the B document?

Yes. Mr. Mobley?

MR. MOBLEY: If I can just comment. Sitting on the sides, real quickly, it seems like to me that what we're saying here is this--you're trying to develop a means of communication to deal with specific issues or specific concerns of the consumer, and it seems to me that the original answer here is not really addressing that very well, and we've had some other examples thrown out. And I

think it is important to address the question of the missed cancers, because as I was sitting here just thinking about, listening to you all discuss it, you know, what's the most serious concern I would have for my wife or daughter, and that would be a missed cancer. Do I know--I mean, I certainly understand the realities of it, but I think that is an important piece of information to go back to the facility and to have that facility look at it and say, yes, that's one that was missed and, unfortunately, because of the type cancer it is or--well, wait a minute, our imaging process has a problem, or whatever.

I know there are certain legal aspects to that, but the reality here, we're trying to develop a communications link that I think is very important in the process, maybe actually one of the most important parts of the process, because in inspections and regulations you can only do so much. The feedback you get from the consumers and the people in the system are what does the rest of it. It goes well beyond what you can accomplish with regulations and inspections, et cetera.

Thank you.

DR. MONSEES: I don't have any objection to considering that. I just want to make sure that we all know that it doesn't necessarily mean that there's some fault involved.

DR. SICKLES: The only thing that is tricky in working this out is apparently, according to the word of this, at least my reading of it, is the facility is the one who decides whether the complaint is resolved. At least that seems to be the intent of it. Maybe that's not true.

DR. FINDER: No.

DR. SICKLES: Well, put it this way: When there--maybe I'm misunderstanding. When there is a consumer complaint and the facility addresses the issue and believes that the issue is resolved, then I would assume, you know, there's just something put in the record saying we think this is resolved. But it also says in the regulation that the facility has to report to the accrediting body if there are unresolved consumer complaints. Who decides whether they're resolved?

DR. FINDER: Well, actually, both, because it's not an either/or--or maybe it is. The patient, if they don't believe that the situation has been resolved, can take it to the accreditation body and to us.

DR. SICKLES: I understand that. But from the facility's point of view, if the facility believes that the complaint is resolved, the facility will somehow document this in their own records, and then they'll let it sit, and they won't report it. It's just up to--then it would then be up to the patient or the complainer to go to the

accrediting body or to go to the FDA directly?

DR. FINDER: This is a question--

DR. SICKLES: This is vague.

DR. FINDER: In a sense it isn't because there are situations where there will be a complaint and after the situation has, quote-unquote, been resolved, the patient still won't be happy about the result. The facility may believe that they've done all that they can do, and there are those types of situations, but, in effect, it isn't closed. The patient always has the ability to go further and complain to the accreditation body or directly to us, and they have. We've gotten complaints directly from patients when they feel that what's happening at the facility doesn't meet their expectations. And we've worked with them to try and solve those situations.

DR. MENDELSON: What precisely does happen if the complaint goes beyond the facility and it's unresolved? Who in the accrediting body deals with the complaint? Is that specified? Who in the FDA deals with the complaint if it goes beyond the accrediting body to the FDA? What's the ladder of ascent there for dealing with complaints?

DR. FINDER: I can't address specifically the issue of the accreditation body because I personally don't get that involved with their internal workings. They may be able to answer that more--

DR. MENDELSON: Have you developed that yet?

MS. WILCOX-BUCHALLA: We've had a process in place since the law went into effect to process and follow up on consumer complaints. Any complaint received in writing we have staff that's designated that follows up on complaints. We have a procedure and letters that are used to follow up with the facility and, then when the complaint is resolved, to close the file. And we report to FDA on an annual basis the number of complaints we've received and whether they've been resolved or not.

DR. MONSEES: Correct me if I'm wrong, but haven't some of these complaints been the source of review of the facility by sending a team, including a physicist, a staff person, and a radiologist, to the site to inspect?

MS. WILCOX-BUCHALLA: In fact, that's true. And whether it comes from a consumer, from another physician, from the referring physician, technologist, there is a process to take appropriate action if that's required, depending on what the situation is.

DR. MONSEES: So if you think it's a quality issue, you will send a team out?

MS. WILCOX-BUCHALLA: That's correct. We have a survey process, for those of you who may not be aware, that includes, as Dr. Monsees said, a physician who is one of our clinical image reviewers, a medical physicist, who is also a

reviewer, and then a staff person, who in most cases is a mammo-certified technologist. And so we can go out and investigate the complaint and verify whether, in fact, those problems may exist.

For example, the very first site visit that we did, which was before MQSA, was because it was reported to us that the receptionist was taking mammograms. And so the only way to verify that was to go out there and find out if that was, in fact, true. This was pre-MQSA, and we did that. We were able to verify it, and now because of the law, there are teeth that will impact a site that does those kinds of things.

Does that answer the question?

DR. MONSEES: Yes.

DR. MENDELSON: And may I ask one more question? How many in the last year, for example, of the reviews were--how many consumer complaints ended up with ACR as the accrediting body? And how many of those generated site reviews?

MS. WILCOX-BUCHALLA: I don't have those statistics with me, Dr. Mendelson.

DR. MENDELSON: Approximately? Is it--

MS. WILCOX-BUCHALLA: There is another process that we can also use which is called random film checks. They're not really random. They're targeted. If we have a

complaint about image quality from either a consumer--and probably--Marybeth, do you have a better handle on what those numbers might be? Yes, it's a small number, but it's significant, and it requires a significant effort. It always is prioritized as top of the line to be followed up on.

DR. MENDELSON: And were the resolutions agreed upon to everyone's satisfaction, once the--

MS. WILCOX-BUCHALLA: As far as I'm aware. The point is to get people back to doing the right thing the right way.

DR. FINDER: We deal with complaints in a somewhat similar manner. It goes to the person who is best equipped to deal with it, and the ones that I'm most familiar with are the ones that we've dealt with in terms of patients complaining that they can't get their mammograms. And I can honestly say that it's impressive to see how quickly things get changed when the call is from the FDA. And if you want to say that the complaint was resolved, again, it depends on whose side you're on, but I would say that all of them have been resolved on the patient's side.

Now, whether the facility was happy about that or not, that's a different issue. But as far as we're concerned, that closes it out because those films were released. And, again, it's not just film release. It's any

issue that comes up. And we deal with and have conversations with the accreditation body so that we share information about complaints that we receive, complaints that they receive. So we do work together with all the accreditation bodies to accomplish that.

MS. BROWN-DAVIS: I'd like to ask a question of Pam. You mentioned significant--no, you mentioned small numbers, but significant. I just don't have a sense of what that means in terms of how many.

MS. WILCOX-BUCHALLA: I don't have numbers with me, so I don't want to make any misstatements. I guess what I'm saying is not significant numbers, but significant issues--image quality, unqualified personnel.

Unfortunately, one of the most difficult issues to deal with is the issue of the patient who feels there was a problem with compression. And I don't know that you ever really come up with a good resolution, but as Dr. Dempsey said, one of the most important issues is that the facility needs to deal directly with the patient and work with them to make sure that they're satisfied. That's, as I said, the most difficult issue to deal with. If the images are good, then the compression was important. And the patient needs to be aware that that's part of the process. On the other hand, we usually get in the course of a year three or four women who feel that the compression was excessive, and we

try to work with both the patient and the site to get the women to realize that it is critical and that she should not stop having mammograms because she was unhappy about the compression.

So that's one of the big pieces to me that's important, is the educational issue that we can participate in, but it isn't about stopping a facility from doing something.

I am not sure that I am really giving you the answer that you're looking for.

MS. BROWN-DAVIS: Well, you did mention a number. You said three or four.

MS. WILCOX-BUCHALLA: Of compression issues, right.

MS. BROWN-DAVIS: I'm just trying to get--you know, a small number could be 1,000. I just wanted something specific.

MS. WILCOX-BUCHALLA: And in terms of random film checks and site visits, it's also well under a hundred of facilities that we need to follow up on.

MS. BROWN-DAVIS: Thank you.

DR. MONSEES: Ruth Fischer, did you have a comment pertaining to this subject?

MS. FISCHER: Since the accreditation bodies have reported to us on this issue yearly since they became

accreditation bodies, my best recollection is that for ACR they average less than 50 complaints a year.

DR. MONSEES: Okay. There you go. Thank you.

Yes, Ms. Hawkins?

MS. HAWKINS: One of the things that I'd like to say is that, you know, we're looking in terms of this being an issue where the whole process of MQSA, the focus has been on the industry. It has not been on informing the consumers. And so consumers have yet to learn about these revelations at the depth that they should know, because, you know, even when we have addressed this in past meetings, I've been told that the emphasis, the focus has been on the industry, on those facilities out there. And so when we bring this issue to the consumers, I think we may--it's something that has to be done, and it has to be done realistically and in terms of what FDA is using as serious complaints.

DR. FINDER: Let me just address it in a minor way, the sense that we do try and deal with consumer groups to make sure that they're aware, and I would still agree with you that the average consumer doesn't know enough. So all that means to us is that we've got to continue the work that we're doing. You've got to help us, and the mechanisms that you can come up with to help us get this message out would certainly be appreciated.

We do have mailing lists which we send out to the largest consumer groups to let them know what we're doing, but it then is up to them to pass along the message in the method that they best can. Sometimes they do it, and sometimes they don't. And sometimes they're more or less successful. But we're continuing with that process because, you're right, it doesn't help us if the consumers out there don't know all the issues that they have to address and some of their responsibilities and some of the mechanisms that they have. So it is a learning process. It's a continuation of a learning process, but it's got to work.

DR. MONSEES: And I think as the word spreads and as people become less intimidated from coming forward, I expect the numbers will rise, as you're saying. And I don't think that it's necessarily a bad thing. I don't think it will necessarily reflect the fact that facilities are doing a worse job, but perhaps that people are able to come forward more. We shouldn't necessarily consider that if the numbers rise that means that things are deteriorating. In fact, it's maybe that communication is getting better.

Inspection Finding Levels

DR. MONSEES: Okay. With that I think we'll complete--we're going to move to inspection finding levels because I think it follows more closely and because Mr. Mobley is going to need to leave. So we're going to move to

inspection finding levels--the original document, the bigger one, 67 to 72, 3 in the smaller document. And I think we're going to turn to our regulator here and anybody else on the panel who wants to talk about inspection finding levels. What shall we tell the FDA?

MR. MOBLEY: I have a number of questions. I guess my first comment is I really do appreciate that they retained the three levels of findings and that the changes or proposed finding levels are--you know, I don't believe they're major changes. I have a couple of questions, though. We're on page 69 of the A document, right in the middle, for digital mammography.

It says there, Monitor QC done per manufacturer's recommendation, and that's an L3, and then the next one, Is the manufacturer recommended phantom used with laser films? And that's an L3. And it just seemed to me that in looking at this and comparing these things, I felt that these are both imaging issues, and I felt that imaging issues elsewhere had been addressed as L2 issues. Maybe I'm misreading the importance of their imaging--their part in the imaging system. But I felt those were more appropriately L2 findings.

DR. MONSEES: Why are these even here is my question since we don't have regs for digital.

DR. FINDER: Well, actually, we do have regs for

digital in the sense that there's a statement in the regulations that for non-film screen systems you have to follow the manufacturer's instructions or recommendations. So, in effect, what we're trying to do is prepare for the future. And you're right. There are no machines out there right now, but we're trying to be ahead of the game.

DR. MONSEES: Does that answer your specific question about the level?

MR. MOBLEY: It answers your question.

DR. MONSEES: It did not answer yours.

[Laughter.]

DR. FINDER: The question is should these L3's be L2's. You know, that was the proposal--

MR. MOBLEY: I mean, Bob or Robert, or Robert or Bob, might want to address that. I'm just throwing that out there.

DR. NISHIKAWA: I looked at what other L2's are, and I agree with Mike. L3's should probably be L2's.

DR. MONSEES: Both of them?

DR. NISHIKAWA: Yes.

DR. MONSEES: Are you in agreement with that, Mr. Pizzutiello, L3's and L2's--

DR. PIZZUTIELLO: I don't have any problem with that.

DR. MONSEES: Okay. Yes?

DR. SICKLES: My only question relating to this is: Is your question here related to whether the phantom tests had good results or simply that the facility used the specific phantom recommended by the manufacturer? I'm not sure which issue is being addressed by this question. Is the manufacturer's recommended phantom used could be interpreted simply as did they use the manufacturer's phantom or did they use another one which might have been equivalent? If they were using one that is judged equivalent, it shouldn't be a citation at all.

DR. FINDER: Right. Well, I think what the question here is asking is if they're using a different phantom that hasn't been approved by anybody, and the issue, especially with digital, could be that they could be using--let's say that the typical phantom that they use for film screen when the manufacturer's recommending something else. That's the issue that I believe--and the other thing that I just want to make a mention of is that the overall question about the QA-QC procedures being followed is an L2 here. So if they're not following the procedures, that's an L2. These are sub-questions or specific questions about that. But, you know, we can certainly look at the issue about changing the levels.

DR. SICKLES: I have no objection to changing levels to L2's, but I'd be careful about that third one

about the recommended phantom, simply in terms of making sure that a facility that wants to use a phantom that's different than the manufacturer's that is equivalent or more stringent wouldn't be cited.

MR. MOBLEY: I could agree with that. I guess my perspective in dealing with these kinds of issues is that too many times--and I'm not speaking mammography here. I'm just speaking overall. Too many times we run into someone who uses a new methodology, but they want to hang on to old procedures, when in reality they are not pertinent, and it just becomes a real critical issue. And in this particular thing where you're talking about something where there are not specific standards, not specific regulations, and it's new, I think you've got to hang on to that manufacturer's specifications as long as you can until you can develop those broader regulations.

DR. MONSEES: Yes?

MR. MOURAD: Wally Mourad, FDA. This is apparently a typo. It is L2 in both cases.

[Laughter.]

DR. MONSEES: Thank you.

MR. MOBLEY: Well, that settles that question. All that work I did. Never mind.

Next item--stay close, Wally. You can get us out of here quicker. And you'll identify my biases, I guess, as

we go along here, but here under interpreting physician's qualifications, the new modality training--and it's interesting. New modality training if applicable. I don't understand that. But it's my perspective, following on my comment, it's my perspective when you have new modalities, it's extraordinarily important that people understand what the newness brings them. And I just think that training should be L1. I think people should have the training necessary to deal with a new modality that they are adopting and bringing into their practice.

Now, here I'm assuming I'm addressing somebody bringing it into the routine practice and not necessarily somebody working in the research arena or in the developmental arena of a process. I just believe that should be L1.

DR. MONSEES: I'll call for comments from the panel members. I'd tend to agree, but I'd call for your opinions if you have--do you agree or disagree?

DR. MENDELSON: I think it could be a Level 1. It certainly is important and is serious enough to become a major part of practice. It should be afforded that significance in the inspection levels.

DR. MONSEES: Yes?

DR. DEMPSEY: In point of fact, the whole issue about who's doing stereotactic core biopsy revolves around

that issue right there.

DR. MONSEES: Yes?

DR. PIZZUTIELLO: By making it an L1, you strongly motivate facilities to make sure that every person who's involved in this modality is appropriately trained rather than just a few who are doing it most of the time and somebody who's filling in might not be trained. And it's certainly not in anyone's interest for an untrained person to even fill in. So I support the L1.

DR. MONSEES: Okay.

DR. SICKLES: I support the L1 as well. I think what they mean by if applicable is some facilities won't be using the new modality so it won't be applicable. I guess that's what they meant.

MR. MOBLEY: I guess that's self-evident to me. Why would you be looking at the question at that point?

DR. MONSEES: Likewise, do you want to take the technologist qualification, new modality training, and move that up to an L1, too?

MR. MOBLEY: Certainly. I mean, that's my comment.

DR. MONSEES: Yes, I think we're in agreement with that.

MR. MOBLEY: My next--are we done with that one?

DR. MONSEES: Yes.

MR. MOBLEY: My next issue is on technologist qualifications. Are 40 supervised hours of training adequate? Now that I read that, I'm not sure what that really means. But I also felt like that the technologist is the person that's there, that's doing the procedure. I mean, that's the focal point of the procedure in terms of producing the image. And I felt that that supervised hours of training was important enough to be considered as an L1 finding. But maybe I'm misreading what that supervised hours of--it must be adequate training, 40 supervised hours of adequate training.

DR. FINDER: Right. These are questions as they might appear on the inspection software, and there's going to be guidance, obviously, to the inspectors on how to interpret these things. But what this basically means is: Does this person have the 40 hours, the supervised hours? In other words, is that training adequate?

MR. MOBLEY: Okay. That helps me understand. So it's a yes or no, and if it's a no, then that's an L2 versus an L1.

DR. FINDER: Right.

MR. MOBLEY: What does everybody else think?

DR. FINDER: The other thing, just to put this into some kind of perspective because you don't have all the questions and you don't have all the current levels, what

we've tried to do is separate out those areas that are what we consider the most important, like for a physician we're talking about whether they've had a license to practice medicine. We figure that's an L1. And if you create certain situations where you've considered certain things to be L1, then you look at the other areas, and do you think that they're as important as that. And you try and gauge the process.

There are other things in here that the technologist has to be licensed or certified. That's an L1. So is that as important as some of these other things? And we have to try and grade these things.

The other thing I just want to make mention of, this is the version that's already out for proposal. It's out to the public. For anything that we want to go and up the ante on in terms of raising the level, we have to repropose. I mean, it's not impossible to do. It certainly can be done. But we'd have to repropose again.

DR. MONSEES: So what went out to the public with the typo question, would it have been the 2 or the 3?

DR. FINDER: I don't know what--if that's what went out as the official document--and this may not be the one. Actually, I can check which one went out.

DR. SICKLES: Not being completely familiar with all of the aspects of this--this is just shorthand on this

page for a whole bunch of requirements--I think the most important thing that's done is that the L1's and L2's in terms of personnel requirements are consistent from radiologist to technologist to physicist. And if radiologists become L1 principally because of basic initial education, then technologists should become L1 because of basic initial education. If continuing education rises only to a Level 2, then any aspect of continuing education should just rise to Level 2.

I'm just not sure how these things fit in because they're so shorthanded that I don't know where they are.

MR. MOBLEY: I agree, and I think that comment is probably very pertinent to my thoughts, too, because I did not go back and try to sort this out or fold it into all the other issues that are there.

I did just use this broad perspective of, you know, trying to assure that I felt like they were reasonable, within the range of what I was looking at and my general knowledge.

DR. MONSEES: Do you have any other issues?

MR. MOBLEY: Let me make this one while I'm thinking about it. This is a general comment.

DR. MONSEES: Go ahead.

MR. MOBLEY: Well, I--

DR. MONSEES: Okay. You want to wait until he--

MR. MOBLEY: Well, maybe Ruth or somebody can carry this back to Charlie, but we got a number of different things to review, and as I was reading, doing my homework for the meeting, I thought I read that I only had to actually review one of these, although I tried to look at all of them, but I spent most of my time on Document A. But it was not clearly identified for me which of these documents were what or how they were going to be utilized. And that's--I mean, it bothers me to come to a meeting and say that I'm commenting on something--and I do know that I'm just providing advisory information or comment--and then be told, well, you know, your review's okay but it's etched in concrete down on Constitution Avenue and we can't get a concrete truck in there to fix it for ten years. I could spend my time doing something else, making comments elsewhere, maybe, but that's fine. I just wanted to clarify that.

DR. MONSEES: In the letter that we received--I assume you received the same one--it told us specifically documents we were going to go through.

MR. MOBLEY: Right, but I thought that--

DR. MONSEES: Are you saying that that was not--

MR. MOBLEY: I thought that there was a comment that these were the same, essentially the same documents. Maybe I just misread--wait a minute. These were essentially

the same documents. I thought that's what I had--

DR. MONSEES: Well, there was a previous one that we discussed.

MR. MOBLEY: Okay. Well, that's fine. That's my misunderstanding. Yes, I have further comments.

On page 70, under medical physicist qualifications, new modality training, do you recognize my bias again? It's an L2, and I think it should be L1. The same type of comment even for physicists.

DR. PIZZUTIELLO: What do you mean "even for physicists"?

[Laughter.]

MR. MOBLEY: I consider myself one, having trained as a physicist some years ago. But, I mean, you know, new modalities are new modalities, and you can go into these things, you know--

DR. MONSEES: We're all agreeing with you.

MR. MOBLEY: Okay. Keep me straight.

Item B on that page, page 70, Item B, proposed changes in current finding levels, my comments here are just sort of a generic thing. In Item 1 there, we're going from a number of different levels with different levels of findings to one level of finding. In Item 2 there, we're going from one level of finding to different levels of finding. So I just found that sort of inconsistent. I

don't have a specific comment on either one of them, necessarily. Either way is reasonable. But I thought that going in the opposite direction on two different issues was just kind of interesting.

DR. MONSEES: Do you have a suggestion to improve it or not really?

MR. MOBLEY: Just an observation. I'm just wondering why--if there is a reason to reduce the issues on Item 1 to just one level of finding, then why do we expand on 2 to additional levels of finding?

DR. PIZZUTIELLO: I'd like to respond to that a little bit. The way I interpreted that, I like the two the way these are laid out. The dose level being 350, there's relatively little uncertainty. If you have doses over 350, you have a major problem. That I think is very appropriate as a Level 1.

The step process is very valuable, but there is more uncertainty in knowing exactly what those numbers mean. So if you're way, way off, if you're below 65 when the benchmark should be 100, then, again, that's well below the level of uncertainty. I think that between 80 and 100 that could be--I'm sorry, between 65 and 80 that could be a reasonable level of uncertainty to say you have a serious issue but you don't have to respond within 30 days and come right back. So I think it has to do with sort of the

precision of the measurement indicator that are different between--

MR. MOBLEY: Exactly. And that's one of the things that I thought, but I just felt like, hey, wait a minute, I want to comment on that because I wanted to get that clarified. Thank you.

Page 71, 3A, percentage missing. Maybe the inspectors with their additional training fully and adequately understand this Item A here. But as I read that, that's a really convoluted statement or difficult statement. The fraction of time when QC charting is not done, missed, is calculated as a percentage of the total number of days when mammography is practiced during the worst month of a 12-month period or since the last inspection. And I presume the worst month is the one with the most misses.

DR. MONSEES: That's what I presumed.

DR. FINDER: It's basically looking at a worst-case scenario.

MR. MOBLEY: Right. This is the worst month of your year to determine your worst-case percentage or whatever. I just--that was interesting. It took me a while to figure out exactly what was being said there.

That's the extent of my comments on those issues.

DR. MONSEES: Okay. Dr. Sickles?

DR. SICKLES: I have a problem with what I

perceive as a potential mismatch between 3A and 3C on page 71. This relates to the processor QC charts and percent missing versus number of days out of control. Unless I've read it incorrectly, a facility will at any given level of citation--let's take L1 or L2, because those are the ones that pertain. At either the L1 level or the L2 level, if I were a facility and I wanted to avoid getting cited, I am encouraged to not chart rather than to chart as out of limits, because the penalties are much more severe for being out of limits than they are for being missing.

I don't know whether you have a rationale for this and the thinking is, if you're out of limits and you still do it, you know, you're really a bad person, as opposed to if you just don't do it, you're a bad person but you're not that bad.

On the other hand, if you're a really bad person and you know you're out of limits and you realize that the penalties are less for not charting it, you just won't chart it.

DR. FINDER: Right. This is a point that has been discussed a lot, and a lot of it comes down to the point that you just brought up about knowingly operating when you're out of limits we felt was worse than the situation--and this situation exists where let's say you've been doing your processor QC for the week and you skip Wednesday, but

Tuesday you were in control and Thursday you were in control. Chances are Wednesday you were also in control. Is that as bad as operating when you know that you're out of control? And our feeling was that the citation should be at a higher level for those kind of situations.

Yes, does that encourage in some minds the ability to think, well, I'm better off not even charting? That's one of the problems. Can you force people to--not force but somehow give certain people the idea that there are ways to abuse the system? In some sense, yes, but we try and deal with the facility in general, not the outliers in all those cases. I mean, we feel we're going to catch those people eventually using this system. But we did try and make a differentiation between those that knowingly operate out of control.

DR. SICKLES: Okay. I accept that. I just wanted to point out that it is open for abuse by a really devious person. Hopefully there aren't any out there.

DR. MONSEES: Yes?

DR. PIZZUTIELLO: I think that my own sense is that the number of 30 percent is extremely high. That's allowing facilities to operate very many days, unless I'm misunderstanding this, very many days before they get a Level 1. Anybody could miss a couple of days, but 30 percent is quite large.

My gut sense--and I see 100 or so facilities a year--is that that number could be 20, and you'd still only catch the really worst facilities. If a facility is missing 20 percent of their days in a month, I think that's still quite a significant number. But that's just a gut feeling. It's not based on any science.

DR. FINDER: For an example, the difference between 20 and 30 percent basically is the difference between 6 and 4, depending on the number you pick.

DR. SICKLES: In many months, a facility will operate no more than 20 days. And since the 20 percent is 20 percent or greater, you're really talking about the difference between 3 and 4--4 is the higher level, 3 is the lower level.

I have one more.

DR. MONSEES: Yes. Did you have a comment, too?

MS. HAWKINS: Yes.

DR. MONSEES: Okay. Let's go first to Dr. Sickles.

DR. SICKLES: Okay. I just has one more, and it's a matter of clarification rather than anything else. On page 72, in the medical records, number 6 at the bottom, where you're talking about exam results, I assume here you mean assessment codes. Is that what you mean by exam results? If it is, I'd spell it out, and if it isn't, then

I don't know what you mean. I would just use the word assessment codes or something a little bit more explicit than exam results, because that's kind of a--

DR. FINDER: Right. Again, this is wording that went out as proposed. We're still working on the exact wording as it will appear in the inspection procedures. So I think in the latest version, it actually does have assessment codes.

Wally, can you--he nodded his head.

DR. MONSEES: Ms. Hawkins, did you have a comment?

MS. HAWKINS: Yes. I wanted to ask as for the Level 3, for lack of having a standard operating procedure.

DR. MONSEES: What page is that? I'm sorry.

MS. HAWKINS: For handling consumer complaints, on page 69. I believe the consumer complaint mechanism is a significant issue under the standards, and that should be Level 2.

DR. MONSEES: Page 69, quality assurance, standard operating procedure for infection control, L3; standard operating procedure for handling consumer complaints, L3. So should they be--did you think that consumer complaint should be what?

MS. HAWKINS: I believe it should be Level 2.

DR. MONSEES: Level 2. And how infection control? We're asking for a policy and procedure manual, right,

standard operating procedure?

DR. FINDER: Right. Correct.

DR. MONSEES: First let's address the consumer complaints. Does anybody feel that this should stay an L2 or that it should--

DR. SICKLES: It's an L3 now.

DR. MONSEES: I'm sorry, stay an--I'm saying the wrong thing. That is should stay an L3 or should be elevated to an L2? Dr. Sickles?

DR. SICKLES: I think there is much more rationale for considering consumer complaints as L2 than there would be for the other issue.

DR. MONSEES: I agree. And how about infection control? In view of what we heard yesterday and in view of consumer concern, I think that the least that we can have is expect that there will be a standard operating procedure. I think also it's called for to be an L2. Does anybody disagree with that?

DR. MENDELSON: No.

DR. MONSEES: Okay. Any other issues pertaining to the proposed finding levels? Trish? Patricia Edgerton, State of California.

MS. EDGERTON: Is it my understanding that--or is my understanding correct that these are the only new things from the new regs that will be in the inspection package?

DR. MONSEES: I'd defer to you on that one, Charlie.

DR. FINDER: Yes.

MS. EDGERTON: In that case, it concerns me that-- I thought one of the niftiest things that FDA did in the new regs was create a lead interpreting physician who is finally responsible for understanding QA and QC because that's a huge problem. And I don't see that that's inspected against, nor is there any documentation that the quality control technologist has been designated, and are these people doing their jobs, especially the lead interpreting physician.

DR. MONSEES: So you want to see levels and a checkpoint where the inspector will ask those questions?

MS. EDGERTON: I would definitely suggest you see documentation that they have designated a lead interpreting physician and that he does carry out his duties.

DR. MONSEES: Okay. How do you feel?

MR. MOURAD: May I response?

DR. MONSEES: Yes, please.

MR. MOURAD: Wally Mourad again. This is buried under the personnel assignments in the QA program. That includes the lead interpreting physician, the QC technologist, and the medical physicist.

DR. MONSEES: I'm sorry. Where would that be?

MR. MOURAD: You don't see it in there.

[Laughter.]

DR. MONSEES: It's not a typo, though.

MR. MOURAD: Right now we do have a question about personnel assignments in the QA program, and this question is reiterated again under the final regs.

DR. MONSEES: Okay. It sounds appropriate.

Any other questions pertaining to levels here?

[No response.]

DR. MONSEES: Okay. We're going to--before we move on to breast implants and then definitions, I just want to revisit a couple things.

One, the missing page 25, QA general, those three people on this side of the table did not have page 25. Did you do your homework? Okay. Did you have any questions or other suggestions now that you have that missing page?

[No response.]

DR. MONSEES: Okay. So that's taken care of.

Another thing that I want to revisit is infection control, and we had a heated discussion yesterday, and rather than leave this unsaid, I would like to address one of the concerns that was raised yesterday during the public hearing, and that is that the manufacturers seem to have, at least by the presentation, ambiguous guidelines. I was wondering if there are any manufacturers in the audience

that would like to comment on whether or not they feel that there would be any difficulty in coming to draw up a very clear-cut mechanism that institutions could adopt to clean their buckey and their compression plate? Is there any problem with issuing such statements? Can we have some manufacturers answer basically what was raised during the public hearing? Is there a problem with coming up with a clear-cut guideline so that facilities could fall back to manufacturers' recommendations?

Could I please hear from some manufacturers?

MR. SANDRICK: John Sandrick, GE Medical Systems.

I don't work specifically with the infection control part of this. I believe we have developed guidelines. I guess one thing I would say, I have seen our guidelines, and I know what was presented yesterday is only a brief extract of what we include in there. There's much more detail. I'm talking about low-level disinfection, medium-level disinfection, high-level disinfection, and appropriate materials and methods for each level, defining what seems to be appropriate for mammography. So there's more than what was presented yesterday.

I don't know what people's reaction to it is in terms of is it easy to follow or not. I do not get feedback of that type back. But I know it has been discussed with the FDA. There was an FDA guidance document on that. I

think we've gone through that and reviewed the procedures. As I say, I have not done that personally, but I think that sort of procedure has been done.

To your point of whether it's easy to follow, appropriate, I can't really answer that. I don't get that kind of information back.

DR. MONSEES: Okay. That's very helpful to me because that's concordant with what I'm hearing from our infection control people; that is, the level of disinfection has to be coordinated with the level of risk, and in exposures where there's a lot of blood or that kind of thing, there's a different level to the disinfection as to the low-risk situations where skin is put up against it, where cleansing with a disinfectant may be appropriate. So I'm glad to hear that there are different levels. It sounds like those are coordinated.

MR. SANDRICK: As I recall, there are those different levels discussed in our document.

DR. MONSEES: Okay. Yes?

DR. PIZZUTIELLO: John, is this information available on older equipment that's out in the field as well as on new equipment that's being sold?

MR. SANDRICK: It is not available on the oldest equipment. There are probably more cursory guidelines on the oldest equipment. The guidance came out more in line

with some of our more recent equipment over the last couple of years. So, really, the issue was only raised in the last couple of years, and it has been included in operator's manuals for equipment probably introduced in the last couple of years. In reviewing the MQSA requirements, one of our goals is to make guidance available, comparable guidance available on all the different equipment, not that I expect it will be particularly different, but at least if any facility should ask for it, we intend to make it available to them.

DR. MONSEES: Thank you.

Are there any other manufacturers that want to comment on the instructions that are given to facilities, the users of their equipment?

Dr. Sickles?

DR. SICKLES: I think it would be reasonable, unless we hear to the contrary from manufacturers, that they provide, not just on request but maybe on a Website, information on mammography-related equipment infection control, not only for units that they're selling now but for units within reason that they believe may still be in practice, just so that people who have these units have a ready way to get at the information.

DR. MONSEES: I'd like to see that, too, not necessarily on the Website but on request, that such

information for the various levels of risk and how that would be applicable to general practice, I'd like to see that be available for the consumer, being the facility that might look to the manufacturer for that information.

Breast Implants

DR. MONSEES: Okay. Unless there's any other comments, we're going to move forward then to--did you want to make a comment? Okay. All right. We have these agenda items left: breast implants and then definitions. I think we've covered most everything else. Can I see a show of hands from the panel? How many people would like to break for lunch with these agenda items left? I assume, then, that everybody would like to continue. Okay. Thank you. I know that you have to catch a plane.

We're going to next tackle breast implants, pages 61 to 62, the larger document; it's page 36 of the small entity compliance guide.

Go ahead.

DR. SICKLES: Only a comment. The question relating to the use of Eklund procedures, you should know that Dr. Eklund doesn't like these procedures to be given his name. He prefers to call them implant displace views, which are the BI-RADS term also. So I think you're probably better off calling them implant displace procedures.

DR. MONSEES: Can we call it views?

DR. SICKLES: Views.

DR. MONSEES: Whatever. That's my understanding as well. It's more generic. Yes.

Any other comments regarding mammographic procedure and techniques for mammography of patients with breast implants?

DR. DEMPSEY: Barbara, just one comment about kind of the practical day-in, day-out working with patients. And Patricia Wilson might want to comment on this.

Not often, but occasionally, patients will not disclose that they have implants, even when you ask them. And I don't think we can address it in this. I'm just saying that as a practical thing, this comes up. And occasionally it can put a technologist kind of in a bind. But patients on a surprisingly regular basis in our practice--and we're pretty busy--will upon questioning deny that they have implants. And I just want to be sure that that's stated.

DR. MENDELSON: Pete, is this upon being asked specifically if they have implants, not just have you had surgery? Because you can often get a negative in response to that one.

DR. SICKLES: I have to second what Pete says. We have, not infrequently, women who will deny the fact that they've got implants, and there are two reasons--there are

two scenarios. The more common scenario is that in our mobile unit where we discourage imaging women with implants because it's just not set up to do so conveniently, there are some women who, I'm absolutely convinced, purposely are lying about it because they find the mobile unit more convenient to get their service, and they repeatedly deny the presence of implants even though we have flagged their records the last time they came through.

There is a much smaller group of women who will deny implants, even in a scenario where we could easily do the implant occluded views, and I have no explanation for it but it happens.

DR. MONSEES: May I just ask a question here? Because we deal with a lot of patients with implants as well. Are we talking about when they're scheduled or when they actually get in the room? Because it's my understanding once they get in the room--

DR. SICKLES: Both.

DR. MONSEES: --they're very forthcoming. They tell the technologist.

DR. SICKLES: Both.

DR. MONSEES: That's not my experience, but--

DR. DEMPSEY: Both. I will tell you that the last two patients that we've had, I will tell you the reason, and that is, when we've discovered them and showed the film to

the patient, she immediately said, "Don't tell my husband because he doesn't know I have them."

DR. MONSEES: Thank you for sharing that.

[Laughter.]

DR. MONSEES: How should this affect what the FDA-

DR. DEMPSEY: It doesn't. I'm just saying that is a problem.

DR. MONSEES: All right. Any other comments on breast implants?

MS. WILSON: My only comment is all we can mandate is that our employees ask the question. We cannot mandate what the patient replies to us.

DR. MONSEES: Absolutely. I agree wholeheartedly.

Any other comments here?

[No response.]

Definitions

DR. MONSEES: All right. Then we're going to move on, and we're down to definitions. I'm not sure that there's any big discussion that's going to follow here. The only draft guidance document page that I could find was page 4 of that smaller document. Did I miss something? Any other place for definitions? Because I didn't see any others.

DR. FINDER: The other definition, I believe, includes direct notification--not direct notification but

direct supervision.

DR. MONSEES: Oh, under general, where it was under general?

DR. FINDER: Well, there's direct supervision in the first document, Document A on page 16 under the radiologic technologist.

DR. MONSEES: I see. That was page 3, direct supervision means that...

DR. FINDER: Right.

DR. MONSEES: Okay. That was one. And then in the second document, the smaller one, mammographic modality means and qualified instructor means. Do you all see that? That's page 4 of the small document for the mammographic modality and the qualified instructor, and supervision, direct supervision was page 3 of the first document.

Do we want to give any, offer any guidance to FDA regarding these definitions?

DR. FINDER: Let me just say one thing, that direct supervision also appeared for each of the personnel categories, interpreting physician, technologist, and medical physicist, and I believe that they were basically gone over when we went over the major sections.

DR. MONSEES: I think we did. We did. I think we included it under general in the beginning of the discussion. But this page, at least, has not been

previously discussed, page 4 of the smaller document, definitions.

DR. FINDER: And, again, we did discuss at least a part of this when we talked about the mammographic modality.

DR. MONSEES: Right. I think we discussed this actually in another context. You're right. Mammographic modality means a technology within the scope of, blah, blah, blah, basically the 42 USC 263(b) for radiography of the breast. Examples are film screen as your mammography, and there is no other example. Ultrasound is not a modality.

DR. FINDER: The comment was made before to include as the negative, in effect, for ultrasound and MRI, to specifically mention that.

DR. MONSEES: Okay. So are there any other comments pertaining to definitions?

[No response.]

DR. MONSEES: All right. Is there anything we missed or anything we want to revisit? Take a moment to look through your documents and see if you made any notes to yourself. Are there any other comments that we want to offer to the FDA in terms of guidance about their guidance document?

DR. FINDER: One thing I did want to bring up in terms of the technologist and the medical physicist, I believe in the versions that you have, there was a--for

example, on page 10 of the B document, for the continuing experience requirement, you saw the change that occurred there.

DR. MONSEES: Yes.

DR. FINDER: The modification. Those technical amendments actually have been published, so that now is official. So in terms of when people will have to actually meet the requirement, this guidance now is applicable and it actually will be put out.

DR. MONSEES: When they appear on the Website, if there are corrections, are they corrected where they originally were, or do you have to look at some other place on the Website for the newer documents? For example, when this becomes public information, will this be corrected in the original Website document? Do you know what I'm saying?

DR. FINDER: Yes. Well, now that it has become official, we can actually make the changes, and we are able to make the changes on the Website. Obviously we can't make it in the copies that have already been sent to everybody.

DR. MONSEES: Right.

DR. FINDER: But the idea is, again, to use the new electronic mechanisms, the Website, to update and keep everything current so that when there's one change we don't have to send out a huge document again to everybody. We can just notify people that there are these changes.

We have to go through our own process, though, to get, quote-unquote, the official versions through. It takes some time, but, yes, these changes will go into any electronic versions that are available to the public.

The other thing is that we plan to notify facilities as best we can about these changes in addition to those electronic versions, for example, at any of the conferences that we go to, because this especially has been a question that we've been getting a lot of, is when people are going to have to meet this continuing experience requirement. So if you're at a meeting, feel free to announce this if anybody asks--or even if they don't ask--because now it's official.

DR. MONSEES: Yes?

DR. PIZZUTIELLO: At the last meeting, we talked about some of the changes coming out in the Federal Register relating to the collimation, and I had asked if we could be notified as a committee when those came out in the FR since we don't read these things ordinarily, particularly in this case.

DR. FINDER: I can see that you get a copy of the FRs sent to your house.

DR. PIZZUTIELLO: But particularly in this case, since we've all been involved in this process, when the document that's on the Web gets updated, could I ask that

the committee members be notified so that we could know to then go and download the updated copy?

DR. FINDER: Okay. Let me just update you on that. As we talked about, there was already the alternative standard that was approved that we've discussed already. I believe it was last week--within about the last week, a proposed amendment to the performance standard involving collimation was published in the FR. I was hoping that the one for MQSA would have published in time for us to mention it here. It may have just been published. It's going to be within any day or two, I believe. That's what I've been led to believe. So I would say that when you get back home, check the Website. It should be up there. I found the one for the performance standard under our CDRH home page under new FR notices or updates on that. They list all the FRs that come out of the entire center.

So as I say, it was just a few days ago that the performance standard got published--as a proposal, now. And the MQSA one I believe is just a few days behind.

DR. MONSEES: Okay. Did anybody discover--yes?

MS. BROWN-DAVIS: I'd like to revisit this patient notification when there is a problem at a facility. I, too, like Dr. Sickles, although he was thinking about something else last night, slept on something. I slept on this last night, and I just cannot leave it as loose as it is.

Certainly today's--it's on page 65 in the big document, paragraph 2, I guess, at the beginning, the top of the page, the last sentence.

DR. MONSEES: If FDA determines that any activity related to the provision of mammography at a facility may present a serious risk to human health such that patient notification is necessary, the facility shall notify patient or their designees, their physicians, or the public of action that may be taken to minimize the effects of the risk. Such notification shall occur within a time frame and in a manner specified by the FDA.

So now specifically are we talking about time frame again like we did yesterday?

MS. BROWN-DAVIS: Yes.

DR. MONSEES: Okay.

MS. BROWN-DAVIS: It's just too loose, and I think that the FDA needs some guidelines on what is reasonable. I compare it to the automobile industry. This is one of the things that I thought about last night. For instance, if there's an automobile recall as an example, there's a certain amount of time that the manufacturer has to get back to people that have bought that car. It's on the public, you know, to do something about it, to come back in, but there's a specific amount of time that they have to do that. And certainly a woman's mammogram is as important as a

vehicle that he or she may drive.

DR. MONSEES: Okay. That's a good analogy. We offered guidance to the accrediting body regarding the time limit there. What would you propose? And let's see whether that time limit would be feasible because we have to think about what ducks have to be put in a row.

MS. BROWN-DAVIS: Right. I'd be willing to entertain discussion about this and perhaps look at those--you know, perhaps this is an instance when we need to again look at a progressive state, like California as an example, someone that has actually been involved in the process, and see what their guidelines are.

DR. MONSEES: Does the State of California have experience that they could share with us?

MS. EDGERTON: I can answer any specific questions you have. Using your analogy of the automobile industry, they also have to investigate and get to a point where they recognize there's a problem. Once they recognize a problem, there's a time frame. And when we request--when we mandate facilities notify patients, which is only an extreme escalated enforcement, we say they have to do it no later than 30 days. It's a maximum of 30 days.

MS. BROWN-DAVIS: I think when Dr. Monsees asked you yesterday what was the amount of time that a complaint was taken care of, I think you said, if I'm not mistaken,

the next day up to 60 days. So that would make the entire process 90 days, which to me, you know, gives--seems reasonable. I think it could be better, but that seems reasonable.

MS. EDGERTON: Unfortunately, I can envision circumstances that it might take longer than 60 days to investigate.

DR. MONSEES: Well, do we want to put a time frame on the collective or only on from the time they decide whether patient notification needs to occur? Because if we give it for the entire expanse and they find out day one, then you're giving the facility 90 days, and you don't want to give them 90 days once they know. I think once they know, we need to be strict about when they need to notify. Where it's more ambiguous and you don't want to give them that time is how long it's going to actually take to investigate, and that, you know, you're dealing with reputable organizations, accrediting bodies, you're talking about the FDA, that are going to hopefully push this along, unlike a facility that may not be willing to be cooperative, in which case you really want to be strict about it.

Do you understand my point? So how about if we give most of our guidance from the point where it's understood whether patient notification needs to occur? I'd feel comfortable with that. I don't know how you feel about

that.

MS. BROWN-DAVIS: Yes, as long as we can come up with a specific number. I just have a problem with this, nobody having--and although the FDA is a reputable, you know, agency--there's no question about that, but the FDA is made up of human beings who have a number of projects in which they're involved. And the accreditation bodies have a number of things that they're working on. A woman who has received a mammogram at a faulty facility I think has the right to know how long it will be before she is notified.

DR. MONSEES: Right. The question is: How long before they decide whether or not she needs to be notified? And that's where the investigation part comes into play.

MS. EDGERTON: If I could just make one quick comment?

DR. MONSEES: Yes.

MS. EDGERTON: I know that when we get evidence or a complaint that there is a clinical image problem versus, you know, a parking problem at a facility, it does take our utmost attention and we do follow up on it as quickly as possible, and in this one case, you know, doing the targeted clinical image review as a way to finally have a stamp. We have to look at people taking us to court, too, and saying you shut us down or you did this, and we have to respond to FDA and have reasonable explanations for our actions as an

accrediting body. So we want to make sure that we have good evidence and evidence that could possibly stand up in court before we shut down a facility, because we do revoke accreditations of facilities who demonstrate very poor work. So for us, it's like kind of all or nothing. So we want to make sure we're in good shape.

MS. BROWN-DAVIS: Right, and I understand the need to want to give yourself enough time. But I think that it's important that the FDA be willing to more or less regulate the time that you take to get back with the woman who's had the faulty--I know that's difficult, but I think it's imperative, if we're going to get the respect of--much like Ms. Hawkins spoke to earlier, the respect of the consumer community.

DR. MONSEES: How about if we stipulate something like that the accrediting body--because, now, don't forget the serious complaints are going to the accrediting body--that the accrediting body and the FDA make every effort--not to say necessarily every last one, but every effort and maintain documentation about the track record, to determine whether patient notification--or determine whatever endpoint, whether it's patient notification or whether it's resolved, within 60 days and that once a decision is made that patient notification is felt to be necessary, that that be accomplished by the facility within 30 days? Does that

seem reasonable? Can I hear from people here? Is this out of the range of what's accomplishable? Then we're not tying their hands--

MS. EDGERTON: That's certainly what we do today. It's what we do today, because that guidance that when we get a complaint like this that it moves to the front of the line, as far as investigation, and that we would want to keep documentation that we have done everything we can and as quickly and as timely as we can. So it seems reasonable.

DR. MONSEES: I'm going to want to hear also from the large AB, the ACR, as to whether they think that's accomplishable. Yes?

DR. DEMPSEY: I would like to underscore a point that's been made her, and that is, it's very important to dissociate in our talk here the initial investigation time versus what is done after the facts are proven, and also to dissociate between facility, accrediting body, and FDA. Because it's my experience that most complaints can be resolved at a facility level if the proper channels are followed, but the time frame--and this is addressing my comments to Carolyn--the time frame for investigation is extraordinarily variable. It could be as short as a day or two, but it could be weeks.

We currently have a problem of a written report that went to an inappropriate person that was brought to our

attention by the patient, and, you know, we're three, almost four weeks out, trying to figure out how this happened, and we still haven't gotten it. But the patient knows, because we've been back to her several times, that this is ongoing.

The most important element in this process is continued communication with the patient so that she knows that this is being pursued with due diligence. But I think you have to separate the investigative process from what happens after the facts are unequivocally established. And I agree with California. Once that's known, you can move pretty quickly.

DR. SICKLES: I'd like to support what you just laid out in your summary, giving guidelines of what we expect to be close to an upper limit for investigation and then a very specific time for action once action is deemed necessary.

Unfortunately, there is another aspect over which we have absolutely no control in cases that may eventually require patient notification, and that is that it could take six months from a time that a given woman had a mammogram until even a complaint was made relative to her mammogram. So I don't think we'll ever be able to have a situation where anyone can say to a woman, unfortunately, you know, if you haven't heard anything from the FDA within 90 days you know your mammogram was good, because it could be that she

had a mammogram; six months later, somebody finds out there was a problem at a facility. They go investigate it. It takes another 60 days, and then it could be a lot longer just because nobody knew there was a problem.

DR. MONSEES: That's a given. Yes, I think we--

DR. SICKLES: But we have to understand that.

MS. BROWN-DAVIS: We are talking generally about 90 days from the time that the complaint is filed or made.

DR. MONSEES: Correct.

MS. BROWN-DAVIS: Not from the time--right, to realize, not from the time she's given a mammogram.

MR. PIZZUTIELLO: I support the numbers, and to clarify, I don't think we're talking about reputable or unreputable. We're really talking about self-interest. It is in the interest of the accrediting body and in the interest of FDA to proceed with all due diligence on these issues. It may not be perceived to be in the facility's interest, so that's why I think it makes sense to clamp down tighter on the facility, not because they're not reputable but because it might be perceived to be in their interest. We want to force that hand.

DR. MONSEES: Thank you. I think that's probably a better choice of words. I was struggling for something.

Can we hear from the AB, the ACR, to see whether they think these time limits are appropriate?

MS. WILCOX-BUCHALLA: I certainly think that the 30-day patient notification from when a decision is reached is very reasonable. I can see where there are situations where even with due diligence, 60 days may not be enough time to complete the investigation for a variety of scenarios. We have had scenarios where we've asked one of our reviewers to go out and review a large volume of mammograms from a given facility, as many as 400. I have concerns about the ability to maintain objectivity in looking at those mammograms when you try to do that kind of bulk in a short period of time. So we need to make sure that the processes are reasonable and fair so that women get notified appropriately and not because of some variable that we've introduced by time constraints.

Site visits, when we need to do a sit visit to validate a complaint, depending on where it is, when it is, seasonal problems, we also, if you'll remember--this is because of the military. It's an international program. And so if there is a need to do a site visit outside of the country, that may limit how quickly we can get something scheduled.

So what Dr. Monsees proposed is saying in all--make every effort to deal with it within 60 days but to allow for extenuating circumstances or a step-wise investigation I think makes sense. To set limits that are

concrete--they're not a reg, so they're not going to be concrete, anyway, but to make strong recommendations. And I certainly think that all of the ABs and the FDA are committed to any instance where we are concerned that patients may have had poor mammograms, expediting that in every possible way. That's what we're all about.

DR. MONSEES: Could we tie to that--maybe, I don't know how difficult it would be--that if it doesn't come to closure in the 60 days, that merely the patient--the person who's making the complaint is notified that the investigation is ongoing and that it's more time-consumer so that they would know?

MS. WILCOX-BUCHALLA: Absolutely. And I think Dr. Dempsey's point that open communication with the person who is filing the complaint is critical to making sure that we are responsive.

DR. MONSEES: I'd feel comfortable with that. Do you feel better about that?

MS. BROWN-DAVIS: Much better. ThaNk you.

DR. MONSEES: Will you sleep better tonight?

[Laughter.]

DR. MONSEES: Do you feel comfortable with that?

MS. HAWKINS: I feel comfortable with it, although I think it's--we should be clear about the fact that when we think in terms of patient notification because of a public

health risk, this is going to follow additional mammography review, which is going to be a timely process. And so not to get into that expectation that this could happen in 60--this may happen, you know, at the end of--it may not come to FDA's attention until after surveys are done or surveys or reports, annual reports.

DR. MONSEES: That's right.

MS. HAWKINS: And so it's going to be a bit different from patient notification on a consumer complaint and so forth. I think we ought to make sure we understand that.

DR. MONSEES: Okay. Any other outstanding issues, any other things that we need to revisit before we adjourn?

[No response.]

DR. MONSEES: In terms of what we need to discuss at the next meeting, which we're not sure exactly when that will be, but in the spring, if you have any issues that you'd like me to know about and to bring up with the FDA, please don't hesitate to contact me or Dr. Finder. I'll offer his name.

Thank you very much for your patience and your efforts, and we'll see you in the spring. We're adjourned.

[Whereupon, at 12:10 p.m., the committee was adjourned.]

CERTIFICATE

I, **ALICE TOIGO,** the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.

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